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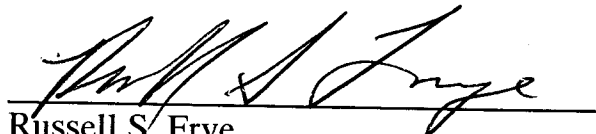
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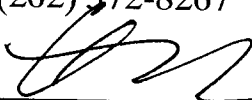
RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Ninth Circuit Rule 26.1, Appellee Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF USA") hereby states that it is a non-profit corporation organized under the laws of the State of Montana. R-CALF USA has no parent corporation, and no publicly traded company owns 10 percent or more of the stock of R-CALF USA.

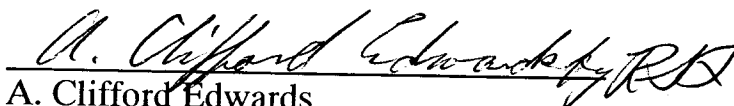
Dated: July 1, 2005



Russell S. Frye
FryeLaw PLLC
P.O. Box 33195
Washington, DC 20033-0195
(202) 572-8267



William L. Miller
The William Miller Group, PLLC
3050 K Street, NW Fourth Floor
Washington, DC 20007
(202) 342-8416



A. Clifford Edwards
Taylor S. Cook
Edwards, Frickle, Anner-Hughes, Cook & Culver
1601 Lewis Ave., Suite 206
P.O. Box 20039
Billings, MT 59104
(406) 256-8155

Attorneys for Plaintiff
RANCHERS CATTLEMEN ACTION LEGAL
FUND UNITED STOCKGROWERS OF AMERICA

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JURISDICTIONAL STATEMENT

Plaintiff-Appellee Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF USA") agrees that this Court has jurisdiction over the Canadian Cattlemen's Association's ("CCA's") and the Alberta Beef Producers' ("ABP's") (collectively, "CCA/ABP") interlocutory appeal of the District Court's denial of their motion to intervene, under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether the district court erred in denying appellants' motion to intervene as of right.
2. Whether the district court abused its discretion in denying appellants' motion for permissive intervention.

STATEMENT OF THE CASE

CCA and ABP filed a joint motion to intervene in R-CALF USA's action, in U.S. District Court for the District of Montana, against the United States Department of Agriculture ("USDA") and the Secretary of Agriculture, seeking

judicial review of USDA's final rule, published January 4, 2005, which among other things allows importation of live cattle and edible bovine products from Canada, subject to some restrictions addressed to the potential for such cattle and meat to be infected with bovine spongiform encephalopathy ("BSE"). 70 Fed. Reg. 460. The District Court denied CCA/ABP's joint motion to intervene as of right or, in the alternative, for discretionary intervention. ER-133. CCA/ABP now bring an interlocutory appeal of that decision. A motion to intervene was also filed by the National Meat Association prior to the preliminary injunction hearing, which motion was denied. ER-122, 126. National Meat Association's appeal of the denial of its motion to intervene has been assigned Ninth Circuit Case No. 05-35214 and is to be heard on July 13, 2005 along with the instant case. Certain Canadian Members of Parliament moved to intervene in R-CALF USA's district court action after the preliminary injunction hearing, and their motion to intervene was denied, but they have not yet appealed that denial of intervention. Supplemental Excerpts of Record ("SER") at 58, 61. (All references herein to "SER" are to R-CALF USA's Supplemental Excerpts of Record, not USDA's.)

Argument on cross-motions for summary judgment is scheduled in the District Court for July 27, 2005. CCA and ABP both moved for leave to file briefs on the summary judgment motions as *amicus curiae*. SER-60. Their

motions were granted, and CCA and ABP filed 20- and 15-page *amicus* briefs, respectively, supporting USDA.¹ ER-110, 112; SER-60. CCA and ABP also each were granted leave to file *amicus curiae* briefs in this Court, in support of USDA's appeal of the District Court's issuance of a preliminary injunction, Ninth Circuit Case No. 05-35264, and they filed 28- and 17-page briefs, respectively, in support of USDA in that case.

STATEMENT OF FACTS

Although R-CALF USA agrees with portions of the Statement of Facts in CCA/ABP's opening brief, that statement omits or mischaracterizes key aspects of the case. First, CCA/ABP imply that the injury they claim to be suffering is solely a result of the District Court's action. In fact, their claimed injuries arise from a longstanding USDA policy, and the policies of most other countries in the world, not to import cattle or beef from countries known to have cattle infected with BSE. USDA has had a policy since 1989 of prohibiting imports of cattle and beef from any country where BSE is known to exist. *See* 70 Fed. Reg. at 462. That policy initially was applied to Canada on May 29, 2003, 68

¹ CCA/ABP note that each chose to limit the issues addressed in these *amicus* briefs. This was neither demanded by the parties nor ordered by the District Court. CCA/ABP's complaint that as *amici* they are precluded from addressing other issues they could have addressed as intervenors is thus a complaint entirely of their own making. *See* CCA/ABP Brief at 10.

Fed. Reg. 31,939, immediately after the discovery of BSE in a native-born cow in Canada. CCA/ABP did not challenge the May 29, 2003 rule.

USDA regulations provide that USDA may issue permits for ruminants or ruminant products to be brought into the United States from countries with BSE in specific cases, where the Administrator determines in the specific case that the action will not endanger livestock or poultry in the United States. 68 Fed. Reg. at 31,940. Under intense pressure from the Canadian government and some U.S.-based meat packers (who also operate packing plants in Canada), on August 8, 2003, then-Secretary of Agriculture Ann M. Veneman announced that USDA would grant blanket permits for the importation of a limited number of meat products from Canada, including boneless bovine meat from cattle under 30 months of age at the time of slaughter, boneless veal from calves under 36 weeks, and fresh or frozen bovine liver. *See* 70 Fed. Reg. 460, 536 (January 4, 2005) (the "Final Rule"). USDA also commenced a rulemaking to consider what additional imports should be allowed from Canada, and on what terms. A proposed rule addressing those issues was published November 4, 2003, 68 Fed. Reg. 62,386.

In the spring of 2004, R-CALF USA learned that, although USDA had told the public that importation of other, higher-risk bovine products from Canada would have to await completion of the rulemaking USDA was

undertaking, in fact USDA had, without notice and comment, authorized imports of those other higher-risk products. R-CALF USA filed an action in federal District Court in Montana, seeking to enjoin imports of these additional products until the rulemaking had been completed. On April 26, 2004, the District Court issued a Temporary Restraining Order, prohibiting importation from Canada of all edible bovine meat products beyond those authorized by USDA's action of August 8, 2003. *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Dept. of Agriculture, et. al.*, No. CV-04-51-BLG-RFC, SER-20. On May 5, 2004, with the stipulation of the parties, that Temporary Restraining Order was converted into a preliminary injunction, which expired after the Final Rule was issued. ER-15.

Contrary to CCA/ABP's assertion that "USDA did not oppose the temporary restraining order requested by R-CALF" (CCA/ABP Brief at 5; *see also id.* at 25-26), USDA vigorously argued against R-CALF USA's request for a temporary restraining order, as is reflected in the District Court's recitation of USDA's arguments in its Temporary Restraining Order opinion (SER-24-25, 28-29). CCA/ABP also falsely imply that USDA's entry into a stipulation, after the Temporary Restraining Order was issued, that avoided a preliminary injunction hearing pending USDA final action on the then-pending BSE rulemaking, indicates that USDA is not committed to defending its regulatory

actions against R-CALF USA's attacks. CCA/ABP Brief at 5-6, 25-26. The District Court had found that USDA clearly had taken final action to allow imports of additional products from Canada without complying with the Administrative Procedure Act, 5 U.S.C. § 553 while at the same time conducting a rulemaking to consider the same issues. SER-27-28. The District Court subsequently ruled, in response to R-CALF USA's request for attorney's fees under the Equal Access to Justice Act, that USDA's position in litigation was "not substantially justified." SER-37. USDA's stipulation to a preliminary injunction until its BSE rulemaking could be completed was, under those circumstances, eminently reasonable and is no indication whatsoever that USDA will not vigorously defend the Final Rule in the proceedings below.

CCA/ABP also falsely imply that USDA suspended the portion of the Final Rule that permitted importation of beef products from Canadian cattle 30 months of age and older because of R-CALF USA's challenge of the Final Rule. CCA/ABP Brief at 26. In fact, CCA/ABP conveniently forget to mention altogether the fact that, right around the issuance and publication of the Final Rule, two additional cases of BSE were reported in Canada, including one in a cow born seven months after Canadian regulations on cattle feed that

supposedly represent a “firewall” to transmission of BSE.² (That fact is also alluded to in the statement by Secretary Johanns announcing the delay, to which CCA/ABP refer, at page 6 of their opening brief.) Again, there is no basis at all for CCA/ABP’s suggestion that this altogether-appropriate suspension of a portion of the Final Rule while these new Canadian cases of BSE are being investigated indicates that USDA will not vigorously defend the Final Rule.

Finally, CCA/ABP’s claims that the “livelihood of CCA/ABP’s members hinges on the outcome of this case” is a misleading overstatement. Because USDA has allowed importation of boneless cuts of beef and veal from Canada as an exception to the general ban on imports, “the United States has continued to import nearly as much Canadian beef since the discovery of BSE in North America as it did before.” Transcript at 78, SER-5; see also Transcript at 79, SER-6 (noting “negligible” impact on Canadian beef market). And the Canadian Beef Export Federation predicts that Canadian beef exports for 2005 will surpass 2004 levels and will be just slightly less than 2002. Dwayne Klassen, “Canada’s 2005 Beef Export Goal Seen as Attainable,” Resource

² See 70 Fed. Reg. 18,252, 18,258 (April 8, 2005); Transcript at 25 (SER-3). This prompted USDA’s counsel to acknowledge in the preliminary injunction hearing that cattle in the Province of Alberta constitute a “high risk population” where there is a “cluster” of BSE (Transcript at 57, 85, SER-4, 7).

News International, April 20, 2005 (available on Nexis, last downloaded July 1, 2005). CCA official John Masswohl was quoted in an AP story last month as believing that, even if the U.S. border remains closed to Canadian cattle, the Canadian cattle business will strengthen. Judith Kohler, "Canadian Cattle Industry Warns Beef Ban May Boomerang on U.S.," AP May 24, 2005, available at <http://www.agweekly.com/articles/2005/05/25/commodities/cattle/cattle02.txt> (last downloaded July 1, 2005). Alberta Agriculture Minister Doug Horner told Canadian Press last week, with respect to Alberta's beef industry, that: "We have what some may consider a stronger industry than we had two years ago," noting that Alberta has increased its slaughter capacity by 30 percent in the two years since BSE was discovered in a native Canadian cow in May 2003. Darcy Henton, "Mad Cow Crisis Made Alberta Beef Industry Stronger: AG Minister," Canadian Press, June 24, 2005 (available on Nexis, last downloaded July 1, 2005). CCA/ABP's plea that their members' livelihood hinges on the outcome of the case below is an exaggeration that infects all of their arguments in favor of intervention.

SUMMARY OF ARGUMENT

CCA/ABP have failed to demonstrate that they are entitled to intervene in the action below. CCA/ABP have the same objective in this litigation as USDA does: to ensure that USDA's new regulation, relaxing restrictions on importation of Canadian cattle and meat, will be upheld and go into effect. CCA/ABP offered no new defenses in their proposed answer, nor did they make any new arguments (at least ones that have any relevance to this proceeding). The facts they suggest they could contribute to the litigation, concerning the economic impact on their members of not implementing the USDA rule, would not constitute grounds for upholding an otherwise invalid rule. CCA/ABP are not in as good a position as USDA to defend USDA's action based on the administrative record, and certainly they have not presented arguments that would overcome the presumption that USDA can properly represent their interest in having the Final Rule upheld.

None of the interests CCA/ABP describe constitutes a personal, legally protected interest justifying intervention in this case, which concerns whether USDA's regulation relaxing BSE-related protections for Canadian cattle and beef was arbitrary and capricious or not in accordance with applicable statutes. CCA/ABP is in no different position than many other businesses and organizations that would benefit from USDA's decision to resume imports of

Canadian cattle and increase imports of Canadian beef. If their undifferentiated financial interests in having USDA's Final Rule go into effect were sufficient to entitle CCA/ABP to intervene as of right, then just about any case concerning judicial review of just about any government regulation would present the opportunity for multiple interests to claim that they have a mandatory right to intervene in order to "help" the agency explain why its action was not arbitrary and capricious based on the administrative record. In fact, in this case there are many such parties waiting in the wings, as the District Court recognized and as this Court is aware from a related case. The District Court correctly decided that the interest CCA/ABP described was insufficient to satisfy the criteria for intervention as of right.

CCA/ABP also failed to make any persuasive arguments showing that the District Court abused its discretion in refusing to grant them permissive intervention, nor did they show that they have a claim that could be raised in the federal district court for the District of Montana that would provide the prerequisite independent grounds for jurisdiction.

ARGUMENT

I. CCA/ABP Failed in Their Burden to Demonstrate Entitlement to Intervene as of Right.

The Ninth Circuit has set out four criteria that all must be met for an applicant to be entitled to intervene as of right: “(1) it has a significant protectable interest relating to the property or transaction that is the subject of the action; (2) the disposition of the action may, as a practical matter, impair or impede the applicant’s ability to protect its interest; (3) the application was timely; and (4) the existing parties may not adequately represent the applicant’s interest.” *United States v. Alisal Water Corp.*, 370 F.3d 915, 919 (9th Cir. 2004), quoting *United States v. City of Los Angeles*, 288 F.3d 391, 397 (9th Cir. 2002). The applicant for intervention has the burden of demonstrating that it meets these criteria. *Alisal*, 370 F.3d at 919. CCA/ABP fail to demonstrate that they met each of those criteria, and therefore the District Court’s denial of their motion to intervene must be upheld.

A. CCA/ABP did not show a particular, legally protectable interest.

CCA/ABP claim an interest in assuring that the Final Rule goes into effect, because the Final Rule will allow their members to sell cattle and additional types of edible bovine products to the United States. As noted in the

Statement of Facts above, even that is an overstatement, since USDA has already been allowing importation of boneless cuts of meat and appeal from Canada, resulting in beef shipments from Canada to the United States continuing at near historical high levels. *See* pp. 7-8, *supra*. But in any event, a mere interest in property that may be impacted by litigation is not a passport to participate in the litigation itself. *Alisal*, 370 F.3d at 920. “To hold otherwise would create a slippery slope where anyone with an interest in the property of a party to a lawsuit could bootstrap that stake into an interest in the litigation itself.” *Id.*

CCA/ABP’s interest in an “unrestricted North American beef market” is a policy goal, not a legally protectable interest. Importantly, it is an interest shared by many other entities (including other trade associations, such as the American Meat Institute and the National Meat Association) that would benefit from the Final Rule and from removal of measures protecting the United States from BSE in Canada. In the related case in which USDA is appealing the District Court’s grant of a preliminary injunction, Ninth Circuit Case No. 05-35264, this Court has received nine *amicus curiae* briefs representing literally hundreds of organizations and individuals that claim to have a similar interest in the implementation of the Final Rule and in unfettered flow of cattle and beef from Canada into the United States.

Allowing CCA/ABP to intervene based on the simple assertion that its members will be better off financially if the Final Rule goes into effect would open up this litigation to many other potential intervenors and start this case down the slippery slope this Court eschewed in *Alisal*. If CCA and ABP are allowed to intervene, then presumably many if not most of the *amici curiae* would have a similar claim for intervention. In fact, if CCA/ABP are entitled to intervene in this case as of right, then in many if not most cases involving judicial review of federal agency actions there may be dozens or hundreds of potential intervenors among the entities that would benefit financially from the agency action. Certainly the District Court was justified in concluding that CCA/ABP failed to show a differentiated, legally protectable interest that justified intervention.

CCA/ABP offer some other, novel arguments for why they have a special interest warranting their intervention as of right. The assertion that CCA/ABP members formerly had contracts to sell cattle and beef to the United States which had to be canceled does not appear to be relevant to their future participation in the case below. See CCA/ABP Brief at 3, 16-17. The notion that they will now make new contracts that might also have to be canceled if imports from Canada continue to be banned under USDA's May 2003 rule suggests an entitlement to export cattle and beef to the United States that

CCA/ABP have not even attempted to demonstrate. *See id.* But in any event, the impact on contracts that they claim is only an indirect one, as the USDA action at issue in the case below does not directly address those contracts at all. And, of course, many other entities could make the same claim, including all of the U.S. parties to those contracts CCA/ABP refers to, and all the other entities involved in cross-border transactions with Canadian cattle and beef that had not yet sought to intervene.

CCA/ABP claim that international treaties designed to avoid discriminatory trade barriers under the guise of health and safety regulations somehow grant CCA/ABP a legally protectable interest that can be pursued in the case below. CCA/ABP Brief at 14-16, 26. But neither the North American Free Trade Agreement (NAFTA) nor the Sanitary and Phytosanitary Standards Agreement modify USDA's obligations under the Animal Health Protection Act or the Administrative Procedure Act, and CCA/ABP have not offered any evidence that they do. In fact, NAFTA specifically provides that U.S. law prevails and that NAFTA does not "amend or modify any law of the United States...regarding – (i) the protection of human, animal, or plant life and health,..." 19 U.S.C. § 3312(a). Nor do those agreements give a private party such as CCA or ABP a legal right to pursue a claim against USDA in federal district court. See NAFTA Implementation Act, 19 U.S.C. § 3312(c). If they

believe that USDA is acting in a manner inconsistent with those agreements, their remedy is to ask their government to pursue dispute resolution mechanisms provided in those agreements (none of which could compel a particular action by USDA in any event).³ In short, reference to these international treaties is simply an unsupportable stretch to try to find some special claim for intervention.

CCA/ABP also claim that they have a legally protectable interest in the reputation of Canadian cattle and beef. CCA/ABP Brief at 19. Their only citation for that argument, *City of Los Angeles*, 288 F.3d at 399, is hardly apposite, since there the allegations against the police officers who sought intervention were specific to those individuals and would have had legal consequences for those individuals if proved. Certainly many others besides CCA/ADP, including notably the many U.S. companies that have imported billions of pounds of Canadian beef and that are represented in many of the *amicus curiae* briefs filed in Case No. 05-35264, share an interest in maintaining a high reputation for Canadian cattle and beef.

³ See also, e.g., *Buell v. Mitchell*, 274 F.3d 337, 372 (6th Cir. 2001); *Macharia v. United States*, 238 F. Supp. 2d 13, 29-30 (D.D.C. 2003); *De La Torre v. United States*, No. C 02-1942, 2004 U.S. Dist. LEXIS 27649 (E.D. Cal. April 14, 2004) (Mexican workers were unable to assert an APA claim against the United States where international agreements did not provide a private right of action).

Finally, it must be noted that, to the extent CCA/ABP have any special interests in the pending litigation, they have already been granted the opportunity to file *amicus curiae* briefs to provide their perspective and legal arguments. Given the procedural mess that would be created if any party with economic interests like CCA and ABP were entitled to intervene as of right, allowing them to pursue their interests through *amicus curiae* briefs is an appropriate resolution. See p. 12-13, *supra*.

B. CCA/ABP failed to show USDA would not protect their interests.

USDA's answering brief does an excellent job of responding to CCA/ABP's claim that USDA would not and could not represent its interests in the district court action. "Under well-settled precedent in this circuit, where an applicant for intervention and an existing party have the same *ultimate objective*, a presumption of adequacy of representation arises." *League of United Latin American Citizens v. Wilson*, 131 F.3d 1297, 1305 (9th Cir. 1997) (internal quotations and citations omitted) (group that had sponsored California Proposition 187 and had the ultimate objective of ensuring that Proposition 187 was upheld as constitutional was adequately represented by California Governor and Attorney General). "If the applicant's interest is identical to that of one of the present parties, a compelling showing should be required to

demonstrate inadequate representation.” *Arakaki v. Cayetano*, 324 F.3d 1078, 1086 (9th Cir. 2003), *citing* 7C Wright, Miller & Kane, § 1909, at 318-19.

CCA/ABP are perhaps careful not to state their ultimate objective in intervention plainly, but it is obvious from their brief and from their proposed answer, filed with their motion to intervene (SER-8). It is to have the Final Rule upheld and go into effect as soon as possible. Obviously, USDA has the very same purpose in this litigation—to see that the Final Rule becomes effective and is implemented. As noted in the Statement of Facts, pp. 5-7, *supra*, CCA/ABP’s suggestion that the Court should presume USDA will not vigorously defend the Final Rule because it allegedly “capitulated” in R-CALF’s challenge to an earlier action easing the ban on imports of Canadian meat is based on a clearly erroneous presumption. Moreover, as USDA notes in its answering brief, it has already been vigorously defending the Final Rule in the District Court and in its appeal of the preliminary injunction to this Court.

Just because CCA/ABP feel they can better describe the economic harm to their members if the Final Rule is found to be arbitrary and capricious or contrary to law does not change the fact that their objective is exactly the same as USDA’s. “Where parties share the same ultimate objective, differences in litigation strategy do not normally justify intervention.” *Id.*, *quoting United*

States v. City of Los Angeles, 288 F.3d 391, 402 (9th Cir. 2002). Furthermore, CCA/ABP claims that their members would be benefited economically by the Final Rule and are being adversely affected economically by the *status quo* are irrelevant to the question before the District Court: whether USDA's action was arbitrary and capricious or not according to law, based on the administrative record. If, in fact, continuing the U.S. policy of banning imports from countries where BSE is known to exist may have adverse financial consequences for CCA/ABP's members, that still would not justify a rule that otherwise is arbitrary and capricious or not according to law. It is unclear how the economic benefits of the Final Rule for foreign nationals might be relevant at all, but in any event USDA has shown an intention to recognize those economic benefits. *See, e.g.*, 70 Fed. Reg. at 536 ("Canadian producers and suppliers of ruminants and ruminant products will clearly benefit from the resumption of exports to the United States."); *id.* at 538 ("the margin earned from slaughtering cows in Canada and exporting the processing beef to the United States is likely to remain favorable").

Nothing here comes even close to the "compelling showing" that USDA will not adequately represent CCA/ABP's interests in having the Final Rule upheld and go into effect. *See Arakaki*, 324 F.3d at 1086.

CCA/ABP have no special advantage in demonstrating to the District Court why USDA's action was supported by the administrative record; to the contrary, USDA obviously is best able to argue why its actions were not arbitrary and capricious or contrary to law. Although there are limited circumstances where the District Court is allowed to go beyond the administrative record in assessing an agency action (*see, e.g., Thompson v. United States Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989); *The Bunker Hill Co. v. EPA*, 572 F.2d 1286, 1292 (9th Cir. 1977)), CCA/ABP make no attempt to explain how any information they may have that is not part of the administrative record would qualify for one of the exceptions to the general rule.

CCA/ABP's proposed responsive pleading (SER-8) also belies their claim that, as intervenors, they would present arguments that USDA could not or would not. Aside from 10 affirmative defenses, none of which have any merit, CCA/ABP's proposed answer adds nothing to USDA's answer (ER-94), nor to USDA's defense of the action below. (In fact, most of those affirmative defenses appear on their face to be subject to sanctions under Fed. R. Civ. P. 11, such as CCA/ABP's claim that R-CALF USA waived its right to challenge the Final Rule, or that R-CALF USA's challenge, filed six days after the Final Rule was published, is barred by a statute of limitations.)

II. CCA/ABP Fail Completely To Show Why the District Court Abused its Discretion in Denying them Permissive Intervention.

The District Court's denial of permissive intervention is reviewed for abuse of discretion. *Southern Calif. Edison Co. v. Lynch*, 307 F.2d 794, 802 (9th Cir. 2002). CCA/ABP have demonstrated no abuse of discretion, merely restating the arguments they made below. CCA/ABP failed to present an independent ground of jurisdiction. As noted above, their claim to have some right under international law is not only unsubstantiated in their brief, it is contrary to establish precedent. *See* pp.14-15, *supra*. The other independent ground they assert is difficult to understand: they claim that CCA/ABP could have brought a declaratory judgment action “to determine the validity of USDA’s Final Rule,” citing 5 U.S.C. § 702. CCA/ABP Brief at 32; *see also id.* at 11. If CCA/ABP are suggesting that 5 U.S.C. § 702 authorizes a declaratory judgment action by a person who wants the court to determine that a regulation is valid, then there is no basis for that whatsoever. If, on the other hand, they arguing that they are entitled to permissive intervention because if they had objections to the File Rule, then they could bring an action against USDA, too, than that interpretation would qualify anyone who supports a regulation to intervene in an action challenging the regulation—hardly an independent grounds for jurisdiction.

CCA/ABP have no independent grounds for jurisdiction, as they have no claim at all against R-CALF USA or against USDA. *See, e.g. Blake v. Pallan*, 554 F.2d 947, 955-56 (9th Cir. 1977). Indeed, the proposed answer that CCA/ABP filed along with their motion to intervene makes no such claim. *See* SER-8. The fact that CCA/ABP's interests describe those of many other potential intervenors (*see* pp. 12-13, 15, *supra*) also argues for the Court to exercise its discretion to deny CCA/ABP's motion.

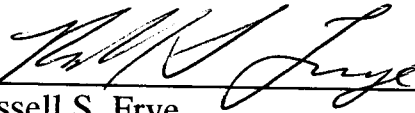
Additionally, in considering whether to grant permissive intervention, a court may consider factors such as whether the intervenor-applicant's interests are adequately represented by other parties to the litigation and whether intervention will prolong or unduly delay the litigation. *Spangler v. Pasadena City Bd. of Educ.*, 552 F.2d 1326, 1329 (9th Cir. 1977). For the reasons described above, CCA/ABP's interests in sustaining the Final Rule clearly are adequately represented by USDA, and allowing CCA/ABP to intervene, when so many other interested parties could also claim a similar basis for intervention as of right, would have unduly prolonged or delayed the litigation.

CONCLUSION

For the reasons set forth above, R-CALF USA respectfully requests that this Court uphold the District Court's denial of CCA/ABP's motion to intervene in the case below.

Dated: July 1, 2005

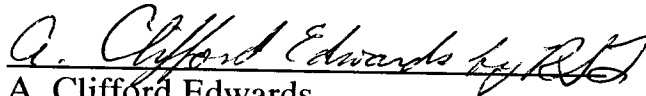
Respectfully submitted,



Russell S. Frye
FryeLaw PLLC
P.O. Box 33195
Washington, DC 20033-0195
(202) 572-8267



William L. Miller
The William Miller Group, PLLC
3050 K Street, NW
Fourth Floor
Washington, DC 20007
(202) 342-8416



A. Clifford Edwards
Taylor S. Cook
Edwards, Frickle, Anner-Hughes, Cook & Culver
1601 Lewis Ave., Suite 206
P.O. Box 20039
Billings, MT 59104
(406) 256-8155

Attorneys for Plaintiff-Appellee

RANCHERS CATTLEMEN ACTION LEGAL
FUND UNITED STOCKGROWERS OF AMERICA

**CERTIFICATE OF COMPLIANCE PURSUANT TO
FED. R. APP. P. 32(A)(7)(C) AND CIRCUIT RULE 32-1**

I certify that:


 X 1. Pursuant to Fed. R. App. P. 32 (a)(7)(C) and Ninth Circuit Rule 32-1, the attached opening/answering/reply/cross-appeal brief is

 X Proportionately spaced, has a typeface of 14 points or more and contains 4639 words (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 14,000 words; reply briefs must not exceed 7,000 words),

Or is

 Monospaced, has 10.5 or fewer characters per inch and contains words or lines of text (opening, answering, and the second and third briefs filed in cross-appeals must not exceed 14,000 words or 1,300 lines of text; reply briefs must not exceed 7,000 words or 650 lines of text).

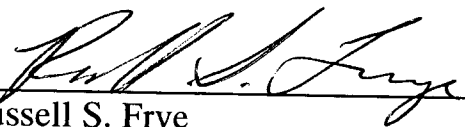
DATED this 1st day of July 2005.


Russell S. Frye
Attorney for Appellee

STATEMENT OF RELATED CASES

Appellee R-CALF USA is aware of two pending case that are related to the instant case: Ninth Circuit Docket No. 05-35264, which is USDA's interlocutory appeal of the District Court's March 2, 2005 issuance of a preliminary injunction in *Ranchers Cattlemen Legal Action Fund United Stockgrowers of America v. U.S. Dept. of Agriculture, et al.*, D. Mont. No. CV-05-06-BLG-RFC, and Ninth Circuit Docket No. 05-35214, which is the National Meat Association's interlocutory appeal of the District Court's February 2, 2005 denial of its motion to intervene in *Ranchers Cattlemen Legal Action Fund United Stockgrowers of America v. U.S. Dept. of Agriculture, et al.*, D. Mont. No. CV-05-06-BLG-RFC.

Those cases will be heard with the instant case on July 13, 2005.


Russell S. Frye
Attorney for Appellee

ADDENDUM OF REGULATIONS

Regulatory Flexibility Act

As Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities because it primarily affects Federal employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this amendatory rulemaking does not contain information collection requirements that require the approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), the final rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

The Office of Government Ethics has determined that this amendatory rulemaking is a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and will submit a report thereon to the U.S. Senate, House of Representatives and General Accounting Office in accordance with that law at the same time this rulemaking document is sent to the Office of the Federal Register for publication in the **Federal Register**.

Executive Order 12866

In promulgating these technical amendments, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have not been reviewed by the Office of Management and Budget under that Executive order, since they are not deemed "significant" thereunder.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this final amendatory regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects**5 CFR Part 2634**

Certificates of divestiture, Conflict of interests, Financial disclosure, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: March 4, 2005.

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

■ For the reasons set forth in the preamble, the Office of Government Ethics is amending 5 CFR parts 2634 and 2635 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 26 U.S.C. 1043; Pub. L. 101-410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104-134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2634.304 [Amended]

■ 2. Section 2634.304 is amended by:

- a. Removing the dollar amount "\$285" in paragraphs (a) and (b) and in example 1 following paragraph (d) and adding in its place in each instance the dollar amount "\$305";
- b. Removing the dollar amount "\$114" in paragraph (d) and in examples 1 and 2 following paragraph (d) and adding in its place in each instance the dollar amount "\$122"; and
- c. Removing the dollar amount "\$285" in examples 3 and 4 following paragraph (d) and adding in its place in each instance the dollar amount "\$305".

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 3. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351; 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2635.204 [Amended]

■ 4. Section 2635.204 is amended by:

- a. Removing the dollar amount "\$285" in paragraph (g)(2) and in examples 1 and 2 (in the latter of which it appears twice) following paragraph (g)(6) and adding in its place in each instance the dollar amount "\$305"; and
- b. Removing the dollar amount "\$570" in example 2 following paragraph (g)(6) and adding in its place the dollar amount "\$610".

[FR Doc. 05-4879 Filed 3-10-05; 8:45 am]

BILLING CODE 6345-02-P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****9 CFR Parts 94 and 95**

[Docket No. 03-080-6]

RIN 0579-AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; partial delay of applicability.

SUMMARY: The amendments in this final rule delay until further notice the applicability of certain provisions of the rule entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities," published in the **Federal Register** on January 4, 2005, 70 FR 460-553. That rule was scheduled to amend the regulations in 9 CFR parts 93, 94, 95, and 96, effective March 7, 2005, to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and to add Canada to this category. That rule included conditions for the importation of certain live ruminants and ruminant products from such regions.

DATES: Effective March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION: On January 4, 2005, we published a final rule in the **Federal Register** (70 FR 460-553, Docket No. 03-080-3) that establishes a category of regions that present a minimal risk of introducing

bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and that adds Canada to this category. The rule also establishes conditions for the importation of certain live ruminants and ruminant products from such regions. The rule was scheduled to become effective on March 7, 2005.¹

Pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, this document delays the applicability of the provisions in that rule as they apply to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver;² (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

If the courts allow the January 4, 2005, rule to go into effect while this delay of applicability is in effect, the commodities listed above that are derived from bovines less than 30 months of age when slaughtered must be accompanied to the United States by certification that (1) the age requirement has been met and (2) the commodity was processed in an establishment inspected by the Canadian Food Inspection Agency (CFIA) that operates in compliance with an approved CFIA program to prevent commingling of ruminant products eligible for export to the United States with ruminant products ineligible for export to the United States. Such certification must be made by a full-time salaried veterinary officer of Canada, or by a veterinarian designated and accredited by the Canadian Government, provided the certification is endorsed by a full-time salaried veterinary officer of Canada who represents that the veterinarian issuing the certification was authorized to do so.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the Department's implementation of this

action without opportunity for public comment is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and 553(d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The delay of applicability is necessary to give Department officials the opportunity for further review and consideration of the specified provisions. Given the scheduled effective date of those provisions, seeking prior public comment on this delay would have been impractical, as well as contrary to the public interest, in the orderly promulgation and implementation of regulations.

List of Subjects

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

■ Accordingly, we are amending 9 CFR parts 94 and 95 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE-FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 94.19 is amended by adding notes at the end of paragraphs (a), (b), and (f) to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

(a) * * *

Note to paragraph (a): The applicability of paragraph (a) to meat, meat byproducts other than liver, and meat food products when such commodities are derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(b) * * *

Note to paragraph (b): The applicability of paragraph (b) to whole or half carcasses derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to gelatin derived from the bones of bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * *

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 3. The authority citation for part 95 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 95.4 is amended by adding notes at the end of paragraphs (f) and (g) to read as follows:

§ 95.4 Restrictions on the importation of processed animal protein, offal, tannage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to tallow derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(g) * * *

Note to paragraph (g): The applicability of paragraph (g) to offal derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * *

Done in Washington, DC, this 8th day of March 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–4917 Filed 3–10–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19470; Directorate Identifier 2003–NM–268–AD; Amendment 39–13997; AD 2005–05–08]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100B SUD, –300, –400, and –400D Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

¹ On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January 4, 2005, final rule is preliminarily enjoined.

² In accordance with an August 8, 2003, announcement by the Secretary of Agriculture, since August 2003 APHIS has issued permits for the importation into the United States from Canada of certain fresh or frozen liver from bovines of any age.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 98

[Docket No. 03-080-7]

RIN 0579-AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rule.

SUMMARY: We are publishing a finding of no significant impact for a final rule concerning bovine spongiform encephalopathy minimal risk regions published January 4, 2005, and, based on that finding, we are affirming the provisions of the final rule. The finding of no significant impact is based on an environmental assessment that documented our review and analysis of potential environmental impacts associated with the final rule and our review of issues raised by the public regarding the environmental assessment. Together, the environmental assessment and our review of the issues raised provide a basis for our conclusion that the provisions of the final rule will not have a significant impact on the quality of the human environment and support our affirmation of the final rule.

DATES: The final rule published January 4, 2005 (70 FR 460), with a partial delay of applicability published March 11, 2005 (70 FR 12112), was effective March 7, 2005. This affirmation of the final rule is effective April 8, 2005.

ADDRESSES: The environmental assessment on which this finding of no significant impact is based may be accessed by any of the following methods:

- On the EDOCKET Web site at <http://docket.epa.gov/edkfed/do/EDKStaffCollectionDetailView?objectId=0b0007d48055a20d>.

- On the APHIS Web site at <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>.

- In the APHIS Reading Room in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

- You may request paper copies of the environmental assessment and the finding of no significant impact by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the titles of these documents when requesting copies.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION:**Background**

On November 4, 2003, the Animal and Plant Health Inspection Service (APHIS) published in the *Federal Register* and requested comment on a proposed rule (68 FR 62386-62405, Docket No. 03-080-1) to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and to add Canada to this category. The proposed rule also included provisions for the importation of certain live ruminants and ruminant products and byproducts from Canada under certain conditions. Also on November 4, 2003, we made available for public comment an environmental assessment (EA) regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts under the conditions of the proposed rule. We carefully considered all comments that addressed the EA, along with those that addressed the proposed rule itself.

On January 4, 2005, we published in the *Federal Register* (70 FR 460-553, Docket No. 03-080-3) a final rule to the proposed rule, to become effective March 7, 2005.¹

Also in the January 4, 2005, issue of the *Federal Register*, we published a notice (70 FR 554, Docket No. 03-080-4) announcing the availability of, and requesting comments on, a final EA regarding the potential impact on the quality of the human environment due

to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in the final rule. APHIS' review and analysis of the potential environmental impacts associated with those importations were documented in the final EA, titled "Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Final Environmental Assessment (December 2004)." We announced that the EA would be available to the public for review and comment until February 3, 2005.

We became aware, however, that the version of the EA that was made available on January 4, 2005, contained some transcription errors that resulted in the omission of several references to an updated APHIS risk analysis regarding the final rule, as well as the incorrect formatting of several source citations. We corrected those errors and, on January 21, 2005, published a notice in the *Federal Register* (70 FR 3183-3184, Docket No. 03-080-5) announcing the availability to the public of the corrected EA and extending the comment period on the EA until February 17, 2005.

We reviewed and considered all issues raised by commenters on the final EA. Of the issues raised by the commenters, some addressed the potential effects of the rule on the environment, while others addressed issues unrelated to such potential effects. Most of these issues had been raised by commenters on the proposed rule and had been previously considered and addressed in our final rule and supporting analyses.

Additionally, shortly after issuance of the final rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF), filed a complaint challenging the rule in the United States District Court for the District of Montana. In that complaint, R-CALF raised several issues regarding the EA that it had not included in either its comments on the proposed rule or in any comment on the final EA. In addition, no other commenter on the EA raised those potential environmental impact issues. Nonetheless, we addressed those issues in our finding of no significant impact (FONSI), discussed below.

We carefully considered environmental issues throughout the rulemaking. Based on the EA and on our review of the comments received on the original and final EAs, on the proposed rule, and in litigation, we have determined that the provisions of our January 4, 2005, final rule will not

¹ On March 11, 2005, the Department published a document in the *Federal Register* (70 FR 12112-12113, Docket No. 03-080-6), effective March 7, 2005, that delayed until further notice the applicability of certain provisions of the final rule. On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of the final rule is preliminarily enjoined.

significantly impact human health or the environment, and that there is no basis in the comments we received and the issues that have been raised to alter the rule. Therefore, we are affirming the final rule as published.

Our FONSI is included in this document under the heading "Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03-080-3), Finding of No Significant Impact." The FONSI includes a discussion of the comments received on the final EA. The EA and FONSI may also be accessed by any of the means listed above under the heading ADDRESSES.

The EA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) SDA regulations implementing NEPA (40 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03-080-3)

Finding of No Significant Impact

United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export, Technical Trade Services, 4700 River Road, Unit 38, Riverdale, MD 20737

This finding concludes the environmental assessment process undertaken for the rulemaking, Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities ("MRR rule"). An environmental assessment ("EA"), dated October 2003, was prepared for this rulemaking and it was made available to the public for comment on November 4, 2003. Comments on the EA were received and carefully considered. A final EA was completed and it was made available to the public on January 4, 2005, for a 30-day comment period. On January 21, 2005, a corrected final EA was made available to the public and the comment period was extended for an additional 14 days until February 17, 2005. The corrected final EA had no changes or additions to the version issued on January 4, 2005, other than the specific references to the latest analysis for the MRR rule that had been inadvertently omitted from the

final EA. This finding summarizes and incorporates by reference the final EA.

Thirteen comments were received in response to our request for comments on the final EA. One was submitted by a state farm bureau federation with certain specific suggestions. This comment counseled caution in implementing the rule for the following reasons. It pointed to the four confirmed cases of bovine spongiform encephalopathy (BSE) in cows of Canadian origin, particularly the most recent diagnosis in a cow that was determined to have been born after implementation of a feed ban in Canada—and recommended that USDA confirm that the Canadian feed ban is being effectively enforced before resuming imports of Canadian cattle under 30 months of age and beef from such younger cattle. Additionally, the comment requested that an effective feed ban have been in place in Canada for a full 8 years before cattle over 30 months of age, and meat from such cattle, are allowed to be imported into the United States. It recommended further review of Canada's surveillance program and asked whether the current level of surveillance in Canada is adequate. The comment supported the animal identification provisions in the rule and recommended that appropriate steps be taken to ensure that all imported cattle were slaughtered before 30 months of age. Finally, the comment noted concerns, which we believe are outside the scope of the environmental assessment, about consumer confidence, our ability to regain access to export markets, and potential impacts on producer returns.

One comment, filed by an individual consumer of beef products who asserted he was not associated with any cattle production or processing business, raised five concerns or issues. These included that there was no quantitative risk assessment in the EA, concern about the duration and effectiveness of Canada's feed ban, concern about the tissues defined as specified risk materials (SRMs) under international standards, concern that public health risk was not adequately analyzed in light of recent diagnoses of BSE in Canada and the levels of feed ban compliance and surveillance in that country, and, finally, a recommendation that an environmental impact statement be completed to study the effect of BSE and TSE disease agents in soil, water, air, and the food chain.

Eight comments—one from a South Dakota organization, one from an Oregon organization, and six from individuals, including an assistant state veterinarian—raised a generally similar

array of concerns. The thrust of these eight comments is that the commenters believe the risk of introducing BSE into the United States weighs against implementation of the rule. The comments noted support for maintaining the current prohibitions on imports of live animals and beef products from Canada, concerns about the effect of importation into the United States of Canadian cattle and cattle products on U.S. export markets, concern about the effectiveness of the Canadian feed ban and the adequacy of Canada's surveillance program, concerns about feeding animal protein of any kind to cows or sheep, a recommendation for country-of-origin labeling, and support for testing for BSE all cattle of Canadian origin that are in the United States. Again, certain of these issues are outside the scope of the EA. Several of the comments also raised questions about the implications of the most recently confirmed BSE-positive animals in Canada on January 2 and January 11, 2005, including the fact that one of these animals was born shortly after implementation of the Canadian feed ban in 1997.

A comment from a pharmaceutical association noted the importance of animal-derived materials in numerous products. This comment was received on February 24, 2005, 7 days after the close of the extended comment period for the final EA. Nevertheless, because, as the commenter pointed out, it had commented in a timely fashion on the proposed rule and its EA comment was intended to update its recommendations based on recent developments, we will respond to this comment. The comment supported the need to revise what it termed the "binary system" of BSE classification of countries and the adoption of what it termed a science-based approach to identifying minimal-risk regions for BSE as outlined in the rule. The comment, therefore, supported implementation of the rule. It recommended permanently identifying cattle from Canada and distinguishing Canadian and U.S.-origin cattle for the sourcing of bovine raw materials, which would allow companies to make sourcing decisions to satisfy BSE regulatory requirements in the countries to which these companies would ship their products. The association supported the implementation of a national animal identification system.

One comment took issue with the notation in the final EA that alkaline hydrolysis tissue digesters were a preferred method of disposal for BSE-contaminated carcasses. It took issue with that conclusion and suggested the commenter's validated protocol and

ness for enzymatic prion degradation, perhaps equally effective. We acknowledge this comment and would welcome more information and data regarding this technology. It is our view, however, that it does not raise an issue that requires discussion in this document. One comment urged the lifting of the prohibitions on camelids because camelids have no demonstrated history of being susceptible to any type of TSE and because these animals are not used for human consumption. We agree with this comment and note that the MRR rule so provided.

Of the issues raised by the commenters, many concerned topics other than the potential effects of the rule on the environment (for example, comments regarding country-of-origin labeling, market access, and consumer confidence). These issues had been addressed by commenters on the proposed rule and were considered and addressed by APHIS in its final rule and supporting analyses. Likewise, most of the commenters who did address the potential effects of the rule on the environment raised issues that had already been raised and addressed at considerable length in the final rule and supporting analyses. This fact illustrates the substantial identity of the central animal and public health issues of the rule and the issues evaluated in the environmental assessments.

It is important to note that issues raised in relation to the two most recent SE-positive cows in Canada on January 11, 2005, will be discussed below. Certain commenters observed that these incidents would call into question the effectiveness and adequate duration of the Canadian feed ban. Because these incidents occurred prior to or immediately before the publication of the final EA, we welcome the opportunity to respond in this comment.

On January 4, 2005, APHIS issued a final rule to amend regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal-risk of introducing BSE into the United States by way of live ruminants and ruminant products and byproducts, and to add Canada to that category. (70 FR 460–553.) The final rule also established conditions for the importation of certain live ruminants and ruminant products and byproducts of minimal-risk regions. Under the Animal Health Protection Act (7 U.S.C. 301 *et seq.*), the Secretary of Agriculture may prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility,

if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. (7 U.S.C. 8303.) The MRR rule will regulate the importation of ruminants and ruminant products and byproducts from Canada in a manner that prevents the introduction of BSE into the United States.

The rule defines a BSE minimal-risk region as one that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

- Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

- Surveillance for BSE at levels that meet or exceed recommendations of the World Organization for Animal Health (Office International des Epizooties or OIE) for surveillance for BSE; and
- A ruminant-to-ruminant feed ban that is in place and is effectively enforced.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

These standards are based upon, and are consistent with, international guidelines issued by OIE. For a full analysis and discussion of these standards, see APHIS' November 4, 2003, proposed rule (68 FR 62388–62389) (please note that some revisions were made to the wording of the proposed standards in the final rule) and the update to our risk analysis.²

APHIS conducted a comprehensive examination and evaluation of all the

relevant risk factors in determining whether Canada qualified as a BSE minimal-risk region. A complete discussion of this evaluation can be found in the risk analysis.³ In summary, APHIS determined that Canada met the standards for a BSE minimal-risk region because:

1. Canada has implemented comprehensive, effective measures for preventing BSE introduction and the potential for spread within Canada in order to minimize the possibility that infected ruminants, ruminant products, byproducts, or contaminated feedstuffs enter the country. The potential for introduction of the BSE agent into Canada has been limited by import restrictions on meat-and-bone meal (MBM) and live animals. Canada's Animal Disease and Protection Regulations (1978) and Health of Animals Regulations (1991) prohibited importation of MBM from countries other than the United States and, later, from Australia and New Zealand. These rules were first initiated in response to foot-and-mouth disease and later extended to address BSE issues. Canada has not imported live cattle from the United Kingdom (UK) since 1990. In 1994, an import ban was imposed on all countries where BSE had been detected in native cattle, and from 1996 live cattle could only be imported from countries that Canada designated as free from BSE following a comprehensive risk assessment. After detection of BSE in an imported animal in 1993, Canada traced and destroyed and incinerated or repatriated all surviving cattle imported from the UK.

2. Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The 2004 OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Since 1992, the surveillance has been targeted surveillance, with samples obtained from adult animals exhibiting some type of clinical signs or considered high risk for other reasons that could be considered consistent with BSE. From January 2004 through March

² See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004," pp. 2–5. This update can be viewed on the Internet at <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>.

³ Ibid, pp. 5–18.

2005, over 37,000 samples were obtained. Canadian Food Inspection Agency (CFIA) officials have stated that this surveillance program is designed to detect one case of BSE in one million adult cattle.

3. Since August 4, 1997, Canada has implemented a ruminant-to-ruminant feed ban that is comparable to that existing in the United States and prohibits the feeding of proteins from ruminant species to ruminant animals. Based on CFIA inspections since 2003, virtually 100 percent of Canadian rendering facilities are in compliance with the ruminant-to-ruminant feed ban requirements applicable to this industry. With regard to inspections of feed mills, CFIA reported that, for an annual inspection period of April to March, the fraction of mills reportedly in compliance was 92 percent, 99 percent, and 95 percent for 2002, 2003, and 2004, respectively.⁴ CFIA has identified noncompliance of "immediate concern" in fewer than 2 percent of feed mills inspected during 2003–2004. Those instances of noncompliance of "immediate concern" are dealt with rapidly when identified. Noncompliance of "immediate concern" includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins. Accordingly, it is clear that Canada's feed ban is effective.

4. Canada conducted rigorous epidemiological investigations after the BSE cases were detected in May 2003 and December 2003 and after the detections in January 2005.⁵ In all but the most recent detection, the cases were animals that were born before the implementation of the feed ban in 1997, with exposure assumed to occur prior to or near the time of the imposition of the feed regulations. The cow in the last detected case was born within a year after implementation of the Canadian feed ban. Although a specific source of infection was not identified, the most likely possibility was the introduction of a low level of infectivity into the animal feed supply originating from an

infected animal imported from the UK in the period between 1982 and 1989. These investigations have resulted in the destruction and sampling of a large number of potentially exposed cattle, and results from all testing have yielded no further evidence of infection. CFIA has traced and destroyed the majority of surviving cattle that were birth cohorts of each of the cases of Canadian origin.

5. CFIA imposed new regulations to further strengthen its safeguards against BSE. Measures taken included requiring the removal of bovine SRMs; enhancing enforcement activities associated with the existing cattle identification system; and increasing the level of BSE testing.

Canada has provided comprehensive information throughout this rulemaking regarding its BSE status and the actions it has taken to protect animal and public health and food safety. The most recent Canadian status update can be accessed through the CFIA 2 Web site at <http://www.inspection.gc.ca/english/anim/heasan/dise mala/bseeb/200503canadae.shtml>.

In summary, the essential factors that led us to conclude that Canada qualified as a BSE minimal-risk region include longstanding Canadian import restrictions, an effective ban on the feeding of ruminant protein to ruminants, the quality of Canada's surveillance and monitoring program, and other measures, such as the required removal of SRMs from cattle at the time of slaughter and enhanced enforcement of Canada's existing mandatory cattle identification system.

APHIS has concluded that the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards provided in the final rule, provide the utmost protection to U.S. consumers and livestock. With respect to Canadian cattle, the MRR rule will allow the importation of:

- Bovines, for immediate slaughter, or for feeding, as long as they are slaughtered at less than 30 months of age;
- Meat from bovines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

The final rule provides the following additional requirements for live Canadian feeder cattle that will ensure they are slaughtered before they reach 30 months of age:

- Feeder cattle must be permanently marked with a brand to identify the BSE minimal-risk region of origin before entering the United States. Feeder cattle exported from Canada will be branded with "C/AN";

- Cattle must be individually identified with an ear tag before entering the United States. This ear tag allows the animal to be traced back to the premises of origin (birth herd);

- Information must be included on the cattle's animal health certification, relating to animal identification, origin, destination, and responsible parties;

- Cattle must be moved to feedlots in sealed containers and cannot go to more than one feedlot; and

- SRMs will be removed from Canadian cattle slaughtered in the United States in accordance with FSIS regulations.

Based on our risk analyses, APHIS concluded that the cumulative effect of all of the measures in place in Canada and the United States, and the additional measures imposed by the final rule, is an extremely effective set of interlocking, overlapping and sequential barriers to the introduction and establishment of BSE in the United States.⁶ The preceding discussion and conclusions provide the foundation for the finding of no significant impact described below.

The final rule was scheduled to become effective on March 7, 2005. On February 9, 2005, the Secretary of Agriculture announced that the provisions of the final rule allowing the importation of beef products from cattle over 30 months of age would be delayed.⁷ On March 2, 2005, the United States District Court for the District of Montana issued a preliminary injunction that enjoined implementation of the MRR rule.

Pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), the purpose of an environmental assessment is to provide sufficient information and analysis to agency decision makers to allow them to determine whether the proposed agency action will have a significant effect on the human environment. If a determination is made that the action would have a significant effect on the human environment, the agency is obligated to prepare an environmental impact statement. If a determination is made that the action will not have a significant effect on the human environment, a finding of no significant impact is issued.

The two EAs issued for the MRR rule considered two alternatives: (1) The "No

⁴ Canadian Food Inspection Agency (CFIA). Memorandum from Dr. Brian Evans, Chief Veterinary Officer, to Dr. John Clifford, Deputy Administrator, VS, APHIS. July 30, 2004.

⁵ Canadian reports of the investigations can be accessed at <http://www.inspection.gc.ca/english/anim/heasan/dise mala/bseeb/bseebindexe.shtml>.

⁶ See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004." pp. 25–27.

⁷ On March 11, 2005, APHIS published a notice in the Federal Register delaying the applicability of the provisions of the rule relating to beef products and byproducts from bovines 30 months of age or older (70 FR 12112).

Action" alternative, which would maintain the continued regulatory prohibition of the importation of ruminants, ruminant products, ruminant by-products from Canada and from any other country or region that could eventually be classified as a BSE minimal-risk region pursuant to the rulemaking and (2) the preferred alternative, which will allow for the importation of certain ruminant products and by-products and certain ruminants, providing the country or region seeking recognition as a BSE minimal-risk region demonstrates that it meets the relevant factors consistent with standards recommended by the OIE.

The environmental issues involved in this rulemaking, including those raised in comments on the two EAs as well as in litigation, are discussed below.

A. The Degree to Which the Action May Affect Public Health or Safety

The introduction of BSE into the United States has the potential to affect both human and animal health. BSE, commonly known as "mad cow disease," is a disease that belongs to a family of mostly very rare diseases known as TSEs. Cases of BSE in cattle were first reported in the UK in 1986. To date, over 95 percent of all known BSE cases worldwide have occurred in the UK. Within cattle herds, BSE is not contagious and does not spread from animal to animal. It is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE. In 1996, a new disease, variant Creutzfeldt-Jakob disease or vCJD, was detected in humans and linked to the BSE epidemic in cattle. Consumption of cattle products contaminated with the BSE agent is reported to be the cause of vCJD. Approximately 153 cases of vCJD have been identified worldwide and 95 percent of these cases have been linked to exposure in the UK. When compared with the significant number of cattle exposed to BSE, the relatively small number of cases of vCJD indicates a substantial species barrier that protects humans from widespread illness due to BSE exposure.

As previously discussed, the MRR rule amends APHIS' regulations to allow the importation of certain ruminants, ruminant products and by-products from regions that pose a minimal risk for BSE. The rule will preclude introduction of BSE into the United States and will ensure the protection of domestic livestock and the food supply. The MRR rule is fully consistent with the guidelines and recommendations of the OIE for trade in

animals and animal products from BSE-affected countries.

In determining whether it was necessary to continue the prohibitions and restrictions on imports from Canada pursuant to the Animal Health Protection Act, APHIS analyzed the risks associated with such imports. The analysis is consistent with OIE guidelines and the internationally recommended components for animal health import risk analysis. The risk analysis drew on a number of sources of information, including: Previous analyses of risk conducted by APHIS; scientific literature; results of epidemiological investigations; data provided by the Canadian Government; a quantitative analysis of the risk of BSE in Canada; quantitative analyses of the consequences of BSE being introduced into the United States; measures implemented by USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) to protect against human exposure to the BSE agent in the United States; reports by international review teams; and the BSE guidelines adopted by the OIE. The determination to allow imports of certain Canadian ruminants and ruminant products was based on a thorough evaluation of the BSE risk in Canada, the potential for BSE infectivity to be introduced into the United States, the potential spread of BSE in cattle and possible human exposure if BSE infectivity were introduced into the United States, and the likelihood that BSE could become established in the United States.

A great deal is now known about BSE. There is a strong scientific consensus about the BSE agent, the mechanisms for its spread, and the tissues that are most likely to harbor the infective agent. Scientific research, backed by practical experience, has resulted in a defined series of measures that countries can use to keep the BSE agent out of the food and feed chain and thus ensure the safety of animal and public health. APHIS has concluded that such measures are in place in Canada and the United States. The risk analysis contains a comprehensive discussion of the facts and circumstances relevant to Canada's BSE status and of the mitigation measures in place in both Canada and the United States that will ensure that BSE is not introduced into the United States. The critical country-of-origin factors leading to APHIS' conclusion and this finding of no significant impact are:

1. *Import Restrictions*—Canada has implemented effective methods for preventing the introduction of BSE into

its herd by restricting the importation of live ruminants and meat-and-bone meal from any country that had not been recognized as BSE-free following a comprehensive risk assessment.

2. *Surveillance*—Canada has been actively monitoring for BSE in its herd since 1992 and has met or exceeded the OIE recommended level of BSE surveillance for the past 7 years. The number of cattle tested annually has steadily increased over the years, and in 2003, approximately 5,700 cattle were tested. In 2004, more than 23,500 animals were tested. In 2005, more than 14,000 samples were tested as of March 23.

3. *Feed Ban*—Canada and the United States implemented substantially identical feed bans simultaneously in 1997 that prohibit the feeding of mammalian protein to ruminants. Canada's feed ban is more stringent than the feed ban in the United States, as it prohibits the use of plate waste and poultry litter in ruminant feed. The Canadian feed ban has been effective and has a strong compliance and enforcement component. It is also important to note that Canada established its feed ban 6 years before identifying its first case of BSE in May 2003.

4. *Epidemiological Investigations*—Canada has the capacity to conduct, and has conducted, rigorous investigations of its BSE findings. These investigations have included trace-outs of cattle that may have been exposed to the same feed sources as infected cattle and of rendered protein products that could have included the tissues from the infected animals. These investigations have been successful due in part to the mandatory cattle identification program in Canada.

5. *Removal of SRMs*—Both Canada and the United States require the removal at slaughter of SRMs—those tissues most likely to harbor the BSE infective agent—and prohibit the use of SRMs in human food.

In addition, there are several biological factors that support the finding herein with specific reference to the importation of live animals and animal products. These factors include: The age of the animal, tissue distribution and infectivity, and feed source and exposure. Our findings with respect to these factors are detailed in the final risk analysis associated with this final rule.⁶ Furthermore, as explained in the exposure assessment

⁶ See "Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities, December 2004," pp. 11–17.

component of the risk analysis, our evaluation of slaughter controls in place in both the United States and Canada, rendering inactivation factors, feed manufacturing controls both in the United States and Canada, and of the likelihood that an animal would ingest an infectious dose and would develop the disease provides further support for our finding of no significant impact.

Finally, the additional post-entry mitigation measures imposed by the final rule enhance protection of animal and human health and further ensure that there will be no significant impacts. The MRR rule requires that live cattle under 30 months of age can only enter the United States for immediate slaughter or for feeding and slaughter. Movement of these cattle is carefully controlled by requiring each animal to have permanent identification that identifies its country of origin, and a special permit designed to account for the inventory of cattle consigned to their point of destination. The rule, therefore, ensures that those cattle are identified and remain accounted for through slaughter.

Based on all these factors, APHIS concluded that there was no scientific basis to believe that the importation from Canada of live ruminants (including cattle less than 30 months of age) and ruminant products (including beef products and byproducts) in accordance with the conditions required in the rule pose any risk of introducing BSE into the United States. For all the reasons discussed in section VI.A. of the final EA, the safeguards in place in both the United States and Canada, coupled with the additional risk mitigation measures required in the MRR rule fully protect both animal and public health.

B. The Degree to Which the Effects on the Quality of the Human Environment Are Likely To Be Highly Controversial or the Degree to Which the Possible Effects on the Human Environment Are Highly Uncertain or Involve Unique or Unknown Risks

Controversy exists when substantial questions are raised as to whether an action may cause significant degradation of an environmental factor. In the context of an EA under NEPA, controversy refers not to the existence of public opposition, but to a substantial dispute about the size, nature, or effect of the action. Even if an action is projected to have a controversial effect, the agency nonetheless has the discretion to be guided by the expertise and judgment, as well as the practical experience, of its own experts. There is a presumption in favor of the agency's expert advice and guidance.

In the case of the MRR rule, there is no significant controversy with regard to the science underlying the mitigation measures that form the basis of the rule, and the effectiveness of the mitigation measures that are in place in Canada and the United States or prescribed as additional requirements in this rule. While questions remain about BSE and research continues on BSE as it does for many animal diseases, there is substantial knowledge about the disease and effective mitigation measures, and a solid scientific consensus among animal health experts both in the United States and internationally. Based upon this substantial body of scientific research, field epidemiological investigations and years of practical experience and observations by animal health authorities, very effective measures have been identified to prevent the introduction and spread of BSE and these measures have been put in place in the United States and Canada and are embodied in the MRR rule.

Two principal concerns are expressed in comments filed on the EA in opposition to the MRR rule. First is the perceived risk that BSE would be introduced into domestic cattle and, second, that vCJD could occur as a result of such introduction or through the import of meat products from Canada. APHIS has concluded that the MRR rule will preclude the introduction of BSE and that the comprehensive animal and public health measures in place in Canada and in the United States will prevent these effects from occurring. In this regard, we must note that while APHIS' principal responsibilities encompass animal and plant health, FSIS and the FDA are the agencies principally responsible for public health and food safety. Both of these agencies have implemented regulations to ensure that the BSE agent does not enter either the human or the ruminant food chain.⁹ In developing the MRR rule and in preparing the EA,

⁹ See: FSIS' interim final rule published in the Federal Register on January 12, 2004, titled "Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1874-1885, FSIS Docket No. 03-025IF.); FDA interim final rule published in the Federal Register on July 14, 2004, titled "Use of Materials Derived from Cattle in Human Food and Cosmetics" (69 FR 42255, FDA Docket No. 2004N-0081); FDA's ruminant feed regulations in 21 CFR 589.2000; and an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS in the Federal Register on July 14, 2004, titled "Federal Measures to Mitigate BSE Risks: Considerations for Further Action" (69 FR 42288-42300, FDA Docket No. 2004N-0264, FSIS Docket No. 04-021ANPR, APHIS Docket No. 04-047-1).

APHIS consulted with both FSIS and FDA.

This rule is based upon and is fully consistent with an international scientific consensus that is embodied in the guidelines and recommendations of the OIE. OIE is the internationally recognized authority on animal health issues and currently has 167 member countries, including the United States and Canada. OIE develops and publishes standards, guidelines and recommendations for international trade in animals and animal products. These standards and guidelines are recognized by the World Trade Organization as the reference international animal health rules for animal diseases and zoonoses and they are codified in the Terrestrial Animal Health Code and the Aquatic Animal Health Code. The standards, guidelines and recommendations are developed by specialist commissions and experts based on the latest and best available scientific research and data and are adopted by consensus of the OIE member countries. The aim of the Terrestrial Animal Health Code is to facilitate the safe international trade of animals and animal products. This is achieved through recommendations on risk management measures for specific diseases to be used by national veterinary authorities or other competent authorities of importing and exporting countries when establishing health regulations for the safe importation of animals and animal products. The aim of the OIE's work in this regard is to avoid the transfer of agents pathogenic for animals and humans, without the imposition of unjustified trade restrictions. With respect to the OIE guidelines for BSE, it is important to note that the OIE does not recommend that an importing country completely ban the importation of live cattle and meat products even when the importing country determines that the exporting country has a high BSE risk status. For the details of the BSE chapter of the Terrestrial Animal Health Code, see http://www.oie.int/eng/publicat/en_code.htm.

Many of the 13 commenters on the final EA opposed implementation of the MRR rule out of a concern that BSE would be introduced into the United States, a concern raised in part by the 2 confirmed cases of BSE in Canada in January 2005. These commenters did not elaborate on the basis for their concern or whether they disagreed with the scientific foundation of the MRR rule. On the other hand, some commenters who expressed concerns about the implementation of the MRR rule acknowledged, implicitly or explicitly, the validity of the scientific

approach embodied in the rule but urged the agency to ensure that the measures the agency relies upon have been effectively implemented. For example, the state farm bureau federation urged that USDA "investigate and confirm" that the current feed ban is being effectively enforced prior to opening the border with Canada. Additionally, the federation urged that USDA assess whether Canada's surveillance program is adequate.

Four cases of BSE have been detected in Canadian-origin cattle. The first two positive cases were detected in 2003 and two cases have been detected in 2005. On January 2, 2005, Canada announced that it had confirmed a case of BSE in an 8-year-old dairy cow in Alberta, Canada.

The following week, on January 11, 2005, Canada announced that it had confirmed a case of BSE in a beef cow in Alberta that was born shortly after the implementation of the feed ban in 1997. Because the cow was born shortly after the implementation of the feed ban and, in addition, to determine if there were any previously unidentified potential links, the USDA sent two technical teams to Canada to evaluate the circumstances surrounding these two recent BSE findings. One team, consisting of USDA and FDA officials, was responsible for conducting an in-depth assessment of Canada's feed ban, and the other team focused on the epidemiological investigations of the positive cases.

In preparing the MRR rule, Canada's compliance with the feed ban was thoroughly considered and discussed. Canada implemented its feed ban in 1997 to prohibit the feeding of most mammalian protein to ruminants. Canada's feed ban is virtually identical to the feed ban in place in the United States, except that Canada has extended its ban by prohibiting plate waste and poultry litter from being fed to ruminants. APHIS concluded, based on this thorough assessment, that Canada has had an effective feed ban in place in the rendering, feed manufacturing and livestock industries. (70 FR 467-468, APHIS Docket No. 03-080-3; "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004," pp. 7-10; see also BSE in Canada Status Update—March, 2005, which can be found at <http://www.inspection.gc.ca/english/animal/heasan/disemala/bseesb/200503canadae.shtml>.)

On February 25, 2005, USDA published its assessment of the Canadian feed ban. The team

concluded, based on its review of inspection records for the last 3 years and on-site inspections of commercial feed mills and rendering facilities, that Canada has a robust inspection program with strong enforcement, that overall compliance with the feed ban is good, and that the feed ban is effectively reducing the risk of transmission of BSE. (<http://www.aphis.usda.gov/lpa/issues/bse/bse.html>.) The team's report confirmed the APHIS evaluation of Canada's feed ban which supported the MRR rule.

It is important to note that in 1997, BSE had not been detected in North America, and the feed bans implemented by Canada and the United States were precautionary measures. As a result, neither government required that existing feed stocks be recalled. In Canada specifically, the feed ban was implemented with provisions for a phase-in period so that existing stocks of feed material could be depleted. It is likely that the Canadian feed ban took some time to be implemented completely throughout the feed manufacturing industry, as did the United States' feed ban. This would be expected in implementing a new, comprehensive regulatory program.

With respect to the two most recent positive BSE cases, the Canadian government confirmed that the animal identified as positive on January 2nd was exposed to feed rations containing meat and bone meal that was produced prior to the 1997 feed ban. This animal was born in October 1996 and was exposed to rations that contained meat and bone meal in early 1997, before the feed ban was implemented. In the case confirmed on January 11th, the Canadian investigation concluded that BSE may have been transmitted to the affected animal through feed produced shortly after the feed ban was implemented. As described in the previous paragraph, since an extensive change in industry practices cannot be expected to be completed immediately, a finding of BSE in an animal born shortly after the feed ban would not be unexpected and would not be inconsistent with the risk analysis supporting the final rule. (See BSE in Canada Status Update—March, 2005, which can be found at <http://www.inspection.gc.ca/english/animal/heasan/disemala/bseesb/200503canadae.shtml>. See also the summary report of the CFIA investigation of the January 2, 2005, case of BSE at <http://www.inspection.gc.ca/english/animal/heasan/disemala/bseesb/ab2005/2investe.shtml> and the summary report of the CFIA investigation of the January

11, 2005, case of BSE at <http://www.inspection.gc.ca/english/animal/heasan/disemala/bseesb/ab2005/3investe.shtml>.)

The possibility of additional BSE positive animals was understood and carefully considered by APHIS in the risk analysis and in our determination that Canada qualifies as a minimal-risk region. In our final rule (70 FR 514), we acknowledged the possibility that additional BSE-infected cattle might exist in Canada and explained the reason for our confidence that the number of such additional infected animals, if any, would be small. First, Canada has not imported ruminant MBM from any country with BSE since 1978. Second, Canada has prohibited the feeding of ruminant MBM to ruminants since 1997, and CFIA has verified high levels of compliance with the feed ban by routine inspections of both renderers and feed mills. Third, Canada has traced and destroyed all remaining cattle imported from the UK. Fourth, Canada has traced and destroyed the majority of the cattle that comprised the birth cohorts of the two initial Canadian BSE cases, as it has subsequently done with the birth cohorts of the two most recent cases. Fifth, Canada has conducted surveillance for BSE since 1992 and has conducted targeted surveillance at levels that have met or exceeded OIE guidelines since 1995.

As we explained in our final rule, even if BSE-infected cattle do remain in Canada, they are likely to be older animals that were exposed before Canada's feed ban in 1997. Because this rule requires that imported animals be less than 30 months old, such animals could not legally enter the United States under this rule. Further, even if an infected animal did enter the United States, the science, the research, and the experience of animal and public health authorities, supported by the Harvard-Tuskegee Study indicates it would be very unlikely to lead to the introduction of BSE into domestic cattle or to human exposure to the BSE agent.

Several commenters on the EA questioned Canada's feed ban due to press reports published in December 2004 that revealed that animal protein of undetermined origin had been found by CFIA in ruminant feed. As part of its ongoing compliance and enforcement program, the CFIA conducted a small feed sampling and testing program to evaluate the usefulness of direct microscopy. CFIA concluded that microscopy was not capable of distinguishing between animal tissues that pose no animal health risk and those that are prohibited under Canada's

feed ban regulations. In following up on the microscopy results, the CFIA concluded the great majority of samples did not contain prohibited material. Of the 110 samples tested, 65 samples were of Canadian origin, 44 samples were from the United States, and one was from France. Of the 65 samples of Canadian origin, the CFIA was unable to rule out the possibility that some incidental level of prohibited material may have been present in 11 samples. Of the 45 imported samples, animal material was detected in 18. With respect to the Canadian origin samples, the CFIA has taken action to ensure that the establishments involved have improved their recordkeeping, flushing, and/or sequencing procedures. (<http://www.inspection.gc.ca/english/animal/feebet/rumin/microe.shtml>.) Based on our extensive experience and interaction with CFIA program officials over many years, the thorough Canadian report on the microscopy sampling and testing program, as well as the results of the APHIS feed team inquiry, APHIS has concluded that the Canadian feed ban is effective and will accomplish its objective of reducing and eliminating any BSE infectivity that may remain in Canada.

As noted above, several commenters expressed concern that the MRR rule could result in the introduction of BSE into the domestic herd and that vCJD could occur as a result of such introduction or through the import of meat products from Canada. With regard to this concern, there is a solid scientific consensus regarding our knowledge of the cattle tissues that contain BSE infectivity and our knowledge of the modes of transmission of that infectivity. While it is likely that ongoing research will increase our knowledge of the disease agent, APHIS, along with FSIS and FDA, are confident that the measures in place will protect animal and human health. In addition, it seems clear that there is a significant species barrier that protects humans from illness due to exposure to the BSE agent. European scientists working on the outbreak in the UK and subsequent BSE research have suggested that the amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. During the epidemic in the UK, it was estimated that there were approximately 1 million infected animals and yet, to date, there have been only approximately 153 vCJD cases worldwide, 95 percent of which have occurred in the UK. Current research does not suggest the need for further food safety mitigations and does not

alter the conclusion that the appropriate tissues that can carry levels of infectivity sufficient to cause human or animal illness are, in fact, being removed from the animal and human food supply under U.S. and Canadian regulations.

One commenter suggested the need for further assessment of the persistence of the BSE agent in soil, water and air. To date, there is no evidence of environmental transmission of the BSE agent. While such transmission could be theoretically possible, epidemiological reviews do not indicate that such transmissions, even if they occurred, would be a significant issue. In the UK, which has experienced the largest and most significant outbreak, early epidemiological investigations pinpointed feed as the route of transmission. In response to these findings, the UK authorities instituted feed ban regulations that have been strengthened over the years. The feed restrictions have clearly had an effect in preventing transmission of disease, with the number of cases identified annually continuing to decrease from a peak in 1992–1993. Investigations have been done on animals born after the reinforced ban went into effect. These have included evaluating all possible routes of transmission, and they continue to conclude that environmental contamination is an unlikely risk factor. Therefore, based on the best available science, the ability of the BSE agent to persist in soil, water and air is not a significant issue.

While there is evidence that scrapie disease in sheep and chronic wasting disease (CWD) in cervids can be transmitted by environmental contamination, there is no basis for extrapolating these data to BSE in cattle. Research has demonstrated that the distribution of scrapie infectivity in sheep is different than the BSE agent in cattle. For example, infectivity has been found in the placenta of sheep infected with scrapie. This contributes to the lateral transmission (animal-to-animal) of scrapie in sheep, and if placental tissue remains in the environment, it can contribute to environmental contamination. Conversely, in cattle infected with BSE, no infectivity has been demonstrated in placenta and there is no evidence of lateral transmission of the disease. Similarly, animal-to-animal contact appears to contribute to the spread of CWD in cervids, and environmental contamination also appears to be a factor, although the specific means of transmission is unknown. However, these findings cannot be extrapolated to cattle with BSE, as there is no evidence

of lateral transmission of BSE or of transmission by environmental contamination.

C. The Degree to Which the Action May Establish a Precedent for Future Action With Significant Effects or Represent a Decision in Principle About a Future Consideration

This criterion requires consideration of whether an action may establish an authoritative rule, pattern, or practice for similar cases that may follow and whether the precedent thereby established could have significant effects on the quality of the human environment.

The MRR rule establishes standards for recognizing regions as presenting a minimal risk of introducing BSE into the United States and provides for the importation of certain ruminants, ruminant products and byproducts from such regions. The minimal-risk region standards and import conditions established by APHIS are designed to prevent the introduction of BSE into the United States. These standards and conditions are buttressed by a series of interlocking, overlapping risk mitigations in place in the United States. The addition of this minimal-risk category to the agency's BSE rules will permit regions that believe they meet the standards to request recognition as a BSE minimal-risk region. We would expect and require that any such request will, in the first instance, comply with § 92.2 of the APHIS regulations, which contains the general procedures for requesting the recognition of regions. (9 CFR 92.2.) The MRR rule, however, designates Canada as the only minimal-risk region for BSE. Before another country or region would be recognized as a BSE minimal-risk region, APHIS would conduct an assessment of all risks involved. If the risk assessment indicated that the region meets the standards and appropriate requirements, APHIS would publish a proposal in the *Federal Register*. At that point, the public would have an opportunity to participate fully and all pertinent issues, questions, and concerns would be addressed in the rulemaking process. Needless to say, any unusual or unique facts or circumstances related to a particular region's request would be carefully evaluated by APHIS as well. For example, the animals or animal products allowed to be imported and the required risk mitigation measures could and would be tailored to each specific region considered. Accordingly, the MRR rule does not establish a precedent for future actions with significant effects or represent a decision in principle about future

approval of additional minimal-risk regions.

D. Whether the Action Is Related to Other Actions With Individually Insignificant but Cumulatively Significant Impacts

The term cumulative impact is defined as an impact on the environment that results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

The potential for harm to the quality of the human environment lies in the introduction of the BSE agent into the United States and subsequently finding its way into the animal and human food supply where it could be ingested and result in infection. For this chain of events to occur, the multiple animal and human health mitigation measures in place in Canada and the United States, as well as the additional mitigations prescribed by the MRR rule, would have to substantially fail. There is no basis to conclude that such a significant breakdown in the system of interlocking and overlapping measures could ever occur. Similarly, if the agency were to recognize any other regions as minimal-risk regions, there is no reason to believe that the mitigation measures and other requirements imposed in such a rulemaking would be any more likely to be breached and result in harm to animal or human health. It must be remembered that our MRR rule is designed to preclude the introduction of BSE into the United States and APHIS has concluded that the rule will achieve that result. Accordingly, there is no basis to believe that this action, or future actions that the agency may take, could result in cumulatively significant environmental impacts.

Additional Issues: Allegations of Environmental Impacts Raised in Litigation

Shortly after issuance of the final EA for the MRR rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America ("R-CALF"), filed a complaint challenging the rule in the United States District Court for the District of Montana. R-CALF alleged that the final EA was inadequate because, among other things, it failed to assess the environmental effects of transporting what we estimated would be as many as 2 million head of cattle from farms and feedlots in Canada to

feedlots and slaughterhouses in the United States, as well as the environmental impacts of feeding and holding these additional feeder cattle until slaughter. Although the plaintiff filed several comments on the rule throughout this rulemaking proceeding, it did not include these concerns in these comments, nor did it file any comment on the final EA published on January 4, 2005. In addition, no other commenter on the EAs raised these potential environmental impact issues. Even though the alleged potential effects pose no significant environmental impact, and were not raised by R-CALF or any other commenter on the EA, we have addressed them below.

The two issues raised by R-CALF did not, and do not now, pose potentially significant impacts. Accordingly, they were not discussed in the final EA. First, it is important to note that the impacts or effects alleged by R-CALF to be significant are not brought about or caused by the MRR final rule. Second, it is also important to understand the MRR rule within the context of the economic relationship that has existed between Canada and the United States for many years. Since the 1970's, the U.S. and Canadian cattle and beef industries operated largely as an integrated North American industry, with both live cattle and processed beef flowing freely between the two countries. For years prior to May 2003, millions of head of live cattle crossed the border in one direction or the other. The two countries have become each other's largest trading partners in agricultural products.

In May 2003, as a result of the finding of BSE in Canada, APHIS published an interim rule to add Canada to the list of countries in which BSE exists. APHIS took this action as a temporary measure while it assessed the facts and circumstances surrounding the BSE situation in Canada. After evaluating the epidemiological investigation of the May 2003 BSE positive cow and after reviewing the BSE risk mitigation measures in place in Canada and the United States, USDA announced in August 2003 that it would begin issuing permits, pursuant to its existing regulations, to allow the importation of certain low-risk meat products from Canada. These products included boneless beef from cattle under 30 months of age, veal, and bovine liver. As a result, within 3 months, a substantial amount of trade in beef and beef products was resumed with Canada. In November 2003, APHIS issued a proposed rule that would again allow the importation of certain live animals, including cattle under 30 months of age,

as well as all beef products from cattle under 30 months of age, from Canada. Therefore, the MRR rule would allow the restoration of trade in ruminants and ruminant products under approved mitigations after a temporary suspension of such trade.

The final economic analysis for the MRR rule estimated that as many as 2 million head of cattle could be imported from Canada in 2005, assuming implementation of the MRR rule at the beginning of the year. This estimate was based on historical cattle import data from 2001 and 2002, an estimated backlog of cattle in Canada as a result of the temporary closure of the border to live cattle in 2003, and an estimate of the number of cattle under 30 months of age that would be available for importation into the United States because of an increase in the number of older cattle that would be slaughtered in Canada for the export of beef to the United States. We acknowledged that there was a good deal of uncertainty in projecting the number of cattle that would be imported from Canada and that changes in production, feeding, slaughter and trade patterns and circumstances could well affect the result. In recognition of these uncertainties, we also conducted the analysis using one-half of the assumed backlog and one-half of the assumed number of imported fed cattle displaced from slaughter in Canada.

Using the 2 million number, R-CALF estimated that the resumption of limited trade in live cattle would result in 35,000 truck round-trips between Canada and the United States. Assuming these would represent an actual increase in trips involving live cattle and meat, the truck traffic represented by this estimation is wholly insignificant. For 2003, the incoming truck crossings from Canada into the United States totaled 13.3 million crossings, which included 6.7 million truck crossings, 5.7 million loaded truck container crossings, and 0.9 million unloaded truck container crossings. (See http://www.bts.gov/programs/international/border_crossing_entry_data/.) For 2002, the total incoming truck crossings from Canada into the United States were 13.7 million crossings, which included 6.9 million truck crossings, 5.8 million loaded truck container crossings and 1.0 million unloaded truck container crossings. (*Id.*) For 2001, the total incoming truck crossings from Canada into the United States were 13.4 million crossings, which included 6.8 million truck crossings, 5.6 million loaded truck container crossings, and 1.0 million unloaded truck container crossings. (*Id.*)

There is little variation in the annual volume of truck traffic entering the United States from Canada over this 3-year period, and, in addition, an increase of 35,000 truck crossings would be well within the variation shown by the data. Even with an increase of 35,000 truck round-trips between Canada and the United States, the total increase would amount to approximately 1/4 of one percent increase in truck traffic, an amount that is *de minimus* by any measure. An examination of truck traffic through the 20 ports of entry through which importations of live ruminants and ruminant products from Canada are authorized under the MRR rule yields similar conclusions. The 2003 truck crossings at the 20 ports of entry were approximately 11.1 million. (*Id.*) Therefore, an increase of 35,000 truck crossings spread over just these 20 ports of entry would result in less than 1/3 of a one percent increase. It is also important to note that truck traffic between the United States and Canada is merely a subset of all vehicular traffic between the two countries. When considering the total volume of all vehicular traffic traveling across the border with Canada, the environmental impacts associated with an increase of 35,000 truck round-trips are even less significant. Accordingly, R-CALF's claim that increased truck traffic would result in environmental damage is without merit.

R-CALF also alleges that there will be significant environmental effects attendant to the importation of live animals for feeding and for slaughter. R-CALF asserts that these live cattle would be required to be moved to a limited number of feedlots and slaughter facilities in the United States. However, the final regulation contains no limitation on the number of feedlots or slaughter facilities. The MRR rule is merely restoring, for live cattle under 30 months, longstanding trade with Canada, trade that has persisted for years and was only temporarily halted in May 2003 due to the finding of BSE in Canada. There is no reason to believe that these cattle would be destined for a different set of feedlots or slaughter facilities than cattle imported from Canada prior to 2003.

Whatever the potential environmental effects that theoretically might be associated with the importation of live cattle for feeding or for slaughter, there would be a significant difference in the magnitude of such potential effects depending on whether the cattle were being transported directly to slaughter facilities or were destined for feedlots, where they may be fed for some period

of time prior to moving to slaughter. The potential environmental effects, while inconsequential, would be significantly less for cattle moved immediately to slaughter facilities. Based on historical data for cattle imports from Canada, between 65 percent and 75 percent of imported cattle have gone directly to slaughter and the remainder (other than the very small number historically imported for breeding) have been transported to feedlots and then to slaughter facilities. Based on the projection in the final economic analysis of 2 million cattle imported, approximately 1.4 million would be moved immediately to slaughter and 600,000 feeder cattle would be moved to feedlots.

Subsequent to the estimates in the final economic analysis and publication of the MRR rule, on February 9, 2005, the Secretary announced that implementation of the part of the MRR rule that would allow for importation of beef from cattle 30 months of age or older would be delayed. Therefore, there was no longer a basis for assuming the displacement from slaughter in Canada of cattle under 30 months of age by cattle 30 months of age or older. The estimate of the number of cattle that would be imported from Canada was revised downward. We further modified the estimate downward to reflect an increase in Canadian slaughter capacity over the past year. Therefore, based on these factors, we estimated that as many as 1.4 million cattle could be imported from Canada in the first year after the effective date of the MRR rule. Of this number, we estimate that 900,000 fed cattle would be moved directly to slaughter facilities and that 500,000 feeder cattle would be sent to feedlots and then to slaughter, further reducing any potential impacts.

On January 6, 2005, the National Cattlemen's Beef Association (NCBA) sent a delegation of U.S. cattle producers to Canada on a fact-finding mission regarding BSE and the MRR rule. One task assigned to the NCBA delegation was to identify Canadian cattle that would qualify for export under the MRR rule and determine the impact on U.S. producers. The NCBA delegation report, dated February 2, 2005 (<http://www.beefusa.org/uDocs/acf985911.pdf>) stated, based on Can-Fax data gathered over a 20-month period of time, that there were approximately 900,000 head of cattle available for export. This consisted of approximately 600,000–700,000 head of fed cattle and approximately 200,000–300,000 feeder cattle. The NCBA report suggested that the import quantities assumed in APHIS' economic analysis were too

high. The NCBA report suggests that the APHIS estimate did not fully account for the 22 percent increase in Canadian slaughter capacity between 2003 and 2004. The NCBA report concluded that the delegation agreed with Can-Fax and other private sector estimates and put the likely imports of feeder cattle in the range of 200,000–300,000 during calendar year 2005 and assumed that the MRR rule would be implemented on March 7, 2005.

Under either of APHIS' two estimates, any environmental effects would not be significant. The average annual number of fed cattle slaughtered for the years 2002 and 2003 in the United States was 29 million. Total cattle slaughter, which includes fed cattle, cows and bulls, averaged 35.6 million head annually for the same period. Thus, the estimated maximum imports of cattle for immediate slaughter would amount to approximately 4.8 percent of the total fed cattle slaughter and 3.9 percent of total cattle slaughter spread over a 12-month period. For the years 2003 and 2004, an average of 26.9 million cattle were marketed by U.S. feedlots annually. The estimated number of feeder cattle that may be imported from Canada in the first year (500,000–600,000 head) would represent between 1.8 and 2.2 percent of fed cattle marketed annually in the United States. Even assuming that Canadian feeder cattle actually imported after implementation of the MRR rule represented an actual increase in the number of cattle on feed in the United States, the potential effects would not be significant. The transitory nature of even this volume of imports from Canada is discussed in the final EA, where estimates that imports would decline over the years 2006–2009 are discussed and displayed.

Furthermore, any potential impacts on air and water quality associated with the importation of cattle from Canada are addressed under an array of existing statutes and regulations in the United States. These regulations include the National Pollutant Discharge Elimination System Permit regulations and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO) under the Clean Water Act, as well as State environmental regulations for proper management of manure and wastewater from animal feedlot operations. In addition to state laws and regulations for air emissions, there are a variety of provisions under the Clear Air Act that could address air emissions relating to this activity. The U.S. Environmental Protection Agency has also established requirements for CAFOs under the

Clean Water Act and regarding nitrate contamination of underground sources of drinking water under the Safe Drinking Water Act. The United States' Clean Air Act and Canadian environmental protection laws have vehicle emissions requirements that are designed to prevent harmful air emissions from vehicles, including transport trucks. These activities have a very low potential to negatively affect human health and safety since each is subject to comprehensive environmental regulation in this country and in Canada. Compliance with these requirements by transporters, feedlot operators, and slaughterhouses assures that the quality of the human environment will be safeguarded in all respects. Our border ports are adequately staffed and capable of handling movement of cattle into this country, which will not concentrate at

a single border port. Historically, Canadian cattle imported into the United States for slaughter have been shipped to numerous States throughout the United States. Because cattle are not required to be shipped to specific feedlots or slaughter facilities, it is expected that trucks will utilize all available border crossings and highway routes. There is no evidence or data to suggest that our roadways, feedlots, and slaughterhouses, as currently operated, cannot accommodate the resumption of Canadian cattle imports in a manner that fully protects all potentially impacted environmental quality values.

I have determined that the final BSE MRR rule will not have a significant effect on the human environment and accordingly I have decided that it is appropriate to issue a finding of no significant impact for the final MRR rule. Thus, having fully considered the two environmental assessments

prepared for the MRR rule, as well as all of the comments submitted on them, along with the reports and analyses referenced in the EA and in the MRR rule, I conclude that the MRR rule will protect animal and human health and the environment. Accordingly, I find that adoption of the MRR final rule and the recognition of Canada as a BSE minimal-risk region will not significantly affect the quality of the human environment.

The finding of no significant impact was signed by Dr. W. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service, on April 5, 2005.

Done in Washington, DC, this 5th day of April 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05-7141 Filed 4-7-05; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****9 CFR Parts 93, 94, 95, and 96**

[Docket No. 03-080-3]

RIN 0579-AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products and byproducts, and we are adding Canada to this category. We are also establishing conditions for the importation of certain live ruminants and ruminant products and byproducts from such regions. These actions will continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on the importation of certain commodities from minimal-risk regions for BSE, currently only Canada.

EFFECTIVE DATE: March 7, 2005.

FOR FURTHER INFORMATION CONTACT: For information concerning ruminant products, contact Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

For information concerning live ruminants, contact Lee Ann Thomas, Director, Technical Trade Services, Animals, Organisms and Vectors, and Select Agents, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

For other information concerning this rule, contact Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION:**I. Purpose**

This document makes final, with changes, a proposed rule that the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department

of Agriculture (USDA or the Department) published in the **Federal Register** on November 4, 2003 (68 FR 62386-62405, Docket No. 03-080-1). In that document, we proposed to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products and byproducts, and to add Canada to this category. The proposal also set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions. We solicited public comment on the proposed rule and its underlying risk analysis and other supporting analyses for 60 days ending on January 5, 2004. At the time the proposed rule was published, BSE had never been detected in a native animal in the United States and only a single case in a native animal had been reported in Canada (in Alberta in May 2003). In December 2003, BSE was detected in an imported dairy cow in Washington State. This document describes the course of this rulemaking before and after the detection in Washington State, including how the rulemaking was affected by additional BSE-related safeguards imposed by USDA's Food Safety and Inspection Service (FSIS) in January 2004. It also responds to public comments received on the proposed rule and its underlying risk analysis and other supporting analyses, both before the original closing date on January 5, 2004, and during an extended comment period that closed on April 7, 2004, and explains the changes we are making in this final rule.

II. Summary of Changes Made in This Final Rule

Based on our continued analysis of the issues and on information provided by commenters, we have made certain changes in this final rule from the provisions we proposed in November 2003, as supplemented by our March 2003 notice of the extension of the comment period. Those changes, summarized in the list below, are discussed in detail in our responses to comments.

1. For bovines imported from a BSE minimal-risk region for feeding and then slaughter (referred to as feeder cattle), we are making the following changes:

- We are requiring that feeder cattle be permanently marked before entry as to country of origin with a brand or other means of identification approved by the Administrator, rather than by an ear tattoo as proposed. Feeder cattle imported from Canada must be marked with "CAN."

- We are requiring that feeder cattle be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin and are specifying that the eartag may not be removed until the animal is slaughtered.

- We are requiring that the animal health certification currently required under existing § 93.405 for certain live animals imported into the United States include, for feeder cattle imported from a BSE minimal-risk region, additional information relating to animal identification, origin, destination, and responsible parties.

- We are requiring that feeder cattle be moved from the port of entry to a feedlot in a sealed means of conveyance and then from the feedlot to a recognized slaughtering establishment in a sealed means of conveyance. The cattle may not be moved to more than one feedlot.

- When referring to the destination of feeder cattle imported into the United States, we are using the terminology "the feedlot identified on the APHIS Form VS 17-130" rather than "designated feedlot."

- We are specifying that the physical location of the feedlot of destination and the person responsible for movement of the cattle be identified on the documentation required for movement from the port of entry to the feedlot.

2. For sheep and goats imported from a BSE minimal-risk region for feeding and then slaughter (referred to as "feeder sheep and goats") we are making the following changes:

- As with cattle, we are requiring that feeder sheep and goats be permanently marked before entry as to country of origin (with the requirements for marking modified as appropriate for sheep and goats). Feeder sheep and goats imported from Canada must be marked with "C."

- As with cattle, we are requiring that feeder sheep and goats be individually identified before entry by an eartag that allows the animal to be traced back to the premises of origin and are specifying that the eartag may not be removed until the animal is slaughtered.

- We are continuing to refer to the feedlot of destination for feeder sheep and goats as a "designated feedlot" and are adding criteria for such feedlots. The sheep and goats may not be moved to more than one designated feedlot.

- We are requiring the same additional information on the health certification required under § 93.405 as described above for feeder cattle.

- We are requiring that feeder sheep and goats be moved from the port of entry to a designated feedlot as a group in a sealed means of conveyance, not be

commingled with any sheep or goats that are not being moved directly to slaughter from the designated feedlot at less than 12 months of age, and be moved from the designated feedlot to a recognized slaughtering establishment in a sealed means of conveyance.

3. For sheep and goats imported from a BSE minimal-risk region for immediate slaughter, we are prohibiting the importation of sheep and goats that are positive, suspect, or susceptible for TSEs.

4. We are moving the provisions for the importation of feeder sheep and goats from Canada from proposed § 93.436 to § 93.405 and § 93.419.

5. We are moving the provisions for the importation of sheep and goats from Canada for immediate slaughter from proposed § 93.436 to § 93.419 and § 93.420.

6. We are clarifying in § 93.420 that all ruminants imported from Canada for immediate slaughter must be moved to a recognized slaughtering establishment in a sealed means of conveyance.

7. We are not specifying in our regulations that the intestines from bovines imported from Canada be removed at slaughter in the United States and be disposed of in a manner approved by the Administrator.

8. We are not including any import restrictions because of BSE for live cervids (e.g., deer, elk) and cervid products from a BSE minimal-risk region.

9. We are specifying that there are no import restrictions because of BSE for camelids (i.e., llamas, alpacas, guanacos, and vicunas) from a BSE minimal-risk region.

10. We are also providing in § 94.18 for the overland transiting of products derived from bovines, sheep, and goats from a BSE minimal-risk region that are eligible for entry into the United States. Additionally, we are clarifying that the existing provisions in § 94.18 for the transiting of ruminant products from regions in which BSE exists or that pose an undue risk of BSE apply only to transiting at air or sea ports.

11. We are requiring that bovines, sheep, and goats imported from a BSE minimal-risk region be subject to a ruminant feed ban equivalent to requirements established by Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services at 21 CFR 589.2000. This is a change from our proposal that the ruminants "are not known to have been fed ruminant protein, other than milk protein."

12. In the definition of *bovine spongiform encephalopathy (BSE) minimal-risk region*, we are rewording

the factor that said a BSE minimal-risk region is one that has "a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban" to say instead that the region is one in which "a ruminant-to-ruminant feed ban is in place and is effectively enforced."

13. We are providing that meat, meat byproducts, and meat food products derived from bovines from a BSE minimal-risk region may not be imported into the United States unless an air-injected stunning process was not used at slaughter and unless the specified risk materials (SRMs) and the small intestine were removed in the exporting region, consistent with the FSIS regulations at 9 CFR 313.15 and 310.22 for stunning and processing in the United States. We are defining SRMs as those materials designated as such by FSIS in 9 CFR 310.22, to include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle.

14. We are removing the proposed requirement that imported meat derived from bovines from BSE minimal-risk regions be derived only from animals less than 30 months of age when slaughtered.

15. We are removing the proposed requirement that meat derived from bovines in a BSE minimal-risk region that are slaughtered in that region come from animals slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with an approved segregation process.

16. We are clarifying that the final rule applies to "meat," "meat byproducts," and "meat food products" as defined by FSIS.

17. We are removing the requirement that hunter-harvested meat be accompanied by a certificate of the national government of Canada.

18. We are clarifying the type of ruminant offal from a BSE minimal-risk region that is allowed importation into the United States.

19. We are providing that tallow may be imported from a BSE minimal-risk region provided the tallow is composed of less than 0.15 percent insoluble impurities and is not commingled with any other material of animal origin.

20. We are providing that, except for gelatin allowed importation under

§ 94.18(c), gelatin imported from a BSE minimal-risk region must be derived from the bones of bovines that were subject to a ruminant feed ban equivalent to the requirements established by FDA at 21 CFR 589.2000 and from which SRMs were removed.

21. We are providing that sheep casings may be imported from a BSE minimal-risk region provided the sheep from which the casings were derived were less than 12 months of age when slaughtered and were subject to a ruminant feed ban equivalent to that of FDA at 21 CFR 589.2000.

22. We are adding and revising definitions in this final rule to clarify the meaning of certain terms used in the rule.

III. Background

A. Bovine Spongiform Encephalopathy

APHIS regulates the importation of animals and animal products into the United States to guard against the introduction of various animal diseases, including BSE. The regulations are contained in 9 CFR parts 92, 93, 94, 95, and 96.

BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and variant Creutzfeldt-Jakob disease in humans. The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke any demonstrated immune response or inflammatory reaction in host animals. BSE is confirmed by postmortem microscopic examination of an animal's brain tissue or by detection of the abnormal form of the prion protein in an animal's brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. BSE is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE.

BSE was first diagnosed in 1986 in the United Kingdom. Since then, there have been more than 187,000 confirmed cases of BSE in cattle worldwide. The disease

has been confirmed in native-born cattle in 20 European countries in addition to the United Kingdom, and in some non-European countries, including Japan, Israel, and Canada. Over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993. Agricultural officials in the United Kingdom have

taken a series of actions to mitigate BSE, including making it a reportable disease, banning mammalian meat-and-bone meal in feed for all food-producing animals, prohibiting the inclusion of animals more than 30 months of age in the animal and human food chains, and destroying all animals showing signs of BSE and other potentially exposed

animals at high risk of developing the disease. As a result of these actions, most notably the feed bans, the annual incidence of BSE in the United Kingdom has fallen dramatically. The figure below illustrates the downward trend in BSE cases among cattle born after implementation of the feed ban.

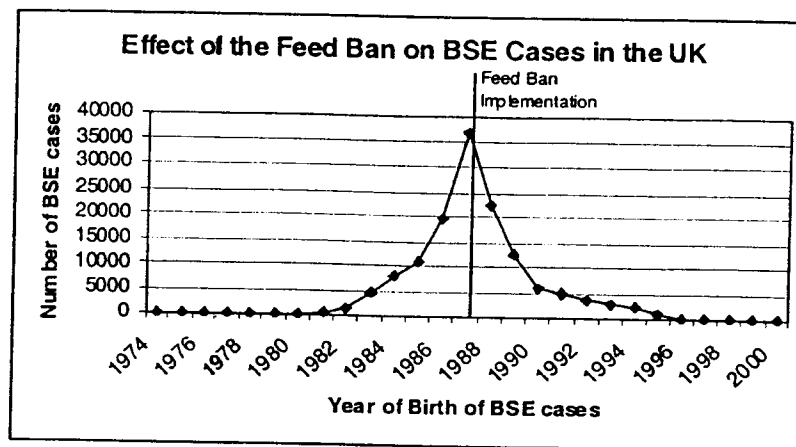


Figure 1.—Confirmed cases in UK cattle born after feed ban implementation. [Note: The first feed ban was implemented in the summer of 1988 (before fall calving).]

Variant Creutzfeldt-Jakob disease (vCJD), a chronic and fatal neurodegenerative disease of humans, has been linked via scientific and epidemiological studies to exposure to the BSE agent, most likely through consumption of cattle products contaminated with the BSE agent. To date, since vCJD was first identified in 1996, approximately 150 probable and confirmed cases of vCJD have been identified. The majority of these cases have either been identified in the United Kingdom or were linked to exposure that occurred in the United Kingdom, and all cases have been linked to exposure in countries with native cases of BSE. Some studies estimate that more than 1 million cattle may have been infected with BSE throughout the epidemic in the United Kingdom. This number of infected cattle could have introduced a significant amount of infectivity into the human food supply. Yet, the number of cases of vCJD identified to date suggest a substantial species barrier that may protect humans from widespread illness due to BSE.

B. APHIS' Regulatory Approach to BSE: Past and Present

Since 1989 APHIS has prohibited the importation of live cattle and other

ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, APHIS added an additional classification of countries as regions of undue risk for BSE and extended importation restrictions on ruminants and ruminant products to all of the countries in Europe. In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species, due to concern that cattle feed supposedly free of ruminant protein may have been cross-contaminated with the BSE agent. The same importation restrictions apply to regions where BSE has been confirmed in a native animal and regions that present an undue risk of BSE because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance (9 CFR 94.18).

In effect then, until implementation of this final rule, countries have fallen into one of three categories with regard to BSE:

- Regions in which BSE is known to exist;
- Regions that present an undue risk of BSE because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance; and
- Regions that do not fall into either of the above two categories.

This regulatory framework recognized only two risk situations—those regions considered free of BSE and those regions considered to present a BSE risk—and prohibited the importation of live ruminants and most ruminant products from those regions considered to present a BSE risk.

In our November 2003 proposed rule, we explained that we believed it was appropriate to establish an additional category of regions with regard to BSE—the BSE minimal-risk region. We stated that regions that could be eligible for a minimal-risk classification would be (1) those regions in which a BSE-infected animal has been diagnosed, but in which measures have been taken that make it unlikely that BSE would be introduced from that region into the United States, and (2) those regions that cannot be considered BSE-free even though BSE has not been detected, but that have taken sufficient measures to be

are a making a nonsubstantive change to § 93.400 to define *flock* as "a group of one or more sheep maintained on common ground; or two or more groups of sheep under common ownership or supervision on two or more premises that are geographically separated, but among with there is an interchange or movement of animals." This definition is the same as the existing definition of *herd* in § 93.400, except that the revised definition of *flock* refers specifically to sheep.

Wording Clarification

We are also amending § 94.18(a)(1) to make it clear that imports of ruminants and ruminant products from Canada are not subject to the restrictions of that paragraph.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 *et seq.*) the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock.

The regulations in 9 CFR parts 93 to 96 include provisions that prohibit the importation of ruminants and most ruminant products (meat and certain other products and byproducts) from (1) regions where BSE exists and (2) regions that present an undue risk of introducing BSE into the United States because of import requirements less restrictive than those that would be acceptable for import into the United States or because of inadequate surveillance.

In this rule, APHIS is establishing an additional category of regions that present a minimal risk of introducing BSE into the United States. This category will include (1) those regions in which a BSE-infected animal has been diagnosed but in which measures have been taken that reduce the risk of BSE being introduced into the United States, and (2) those regions in which BSE has not been detected, but that cannot be considered BSE-free. In this rule, APHIS (1) sets forth the standards the Agency will consider before listing a region as one of minimal risk for BSE, (2) lists Canada as the only BSE minimal-risk region at this time, and (3) establishes measures to mitigate any risk that BSE would be introduced into the

United States through the importation of ruminants and ruminant products from a BSE minimal-risk region. Future requests received from other regions to be considered BSE minimal-risk regions will be evaluated.

On May 20, 2003, CFIA reported a case of BSE in a beef cow in northern Alberta. To prevent the introduction of this disease into the United States, APHIS issued an interim rule that listed Canada as a region where BSE exists, thereby prohibiting the importation of ruminants and most ruminant products from Canada, effective May 20, 2003.

Following the discovery of the BSE-infected cow, Canada conducted an epidemiological investigation of the BSE occurrence, and took action to guard against any spread of the disease, including the quarantining and depopulation of herds and animals determined to be possibly at risk for BSE. Subsequently, Canada asked APHIS to consider resumption of ruminant and ruminant product imports into the United States, based on information regarding the following: Canada's veterinary infrastructure; disease history; practices for preventing widespread introduction, exposure, and/or establishment of BSE; and measures taken following detection of the disease.

The prohibition was modified on August 8, 2003, to allow the importation of certain ruminant-derived products from Canada under APHIS Veterinary Services permit. The most important commodity that can enter by permit is boneless bovine meat from cattle less than 30 months of age.

This study analyzes ruminant and ruminant product imports from Canada that will be allowed to resume because of this rule. Expected benefits and costs are examined in accordance with requirements of the Office of Management and Budget for benefit-cost analysis as described in Circular A-4, "Regulatory Analysis," which provides guidance for agencies on the analysis of economically significant rulemakings as defined by Executive Order 12866. Effects on small entities are also considered, as required by the Regulatory Flexibility Act.

Although not addressed in the analysis, Canadian producers and suppliers of ruminants and ruminant products will clearly benefit from the resumption of exports to the United States. In 2002, about 90 percent of Canadian beef exports and virtually all (99.6 percent) of Canada's cattle exports were shipped to the United States. Canada's cattle producers reportedly had one million more head of cattle on their farms on July 1, 2004, than they

did one year earlier. This increase is largely due to the collapse of Canadian cattle exports.

Below is a summary of our economic analysis. A copy of the full economic analysis is available by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT**. You may also view the economic analysis on the Internet by accessing the APHIS Web site at <http://www.aphis.usda.gov/lpa/issues/bse/bse.html>. Click on the listing for "Economic Analysis, Final Rule, Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (APHIS Docket No. 03-080-3)."

The commodities that will be allowed to be imported from Canada under specified conditions under this final rule can be summarized as:

- Bovines, as long as they are slaughtered at less than 30 months of age, and as long as those bovines not imported for immediate slaughter are moved to a single feedlot before slaughter;
- Sheep and goats (ovines and caprines), as long as they are slaughtered at less than 12 months of age, and provided sheep and goats not imported for immediate slaughter are moved to a single designated feedlot before slaughter;
- Cervids of any age;
- Camelids (*i.e.*, llamas, alpacas, guanacos, and vicunas);
- Meat from bovines, ovines, and caprines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

Model and Assumptions

Cattle and beef imports comprise 99 percent of the value of commodities that will be allowed entry from Canada because of this rulemaking, and they are therefore the focus of the analysis. The model used is a net trade partial equilibrium welfare model. Net trade is defined as the absolute value of the difference between exports and imports. Individual country trade with the United States is not modeled. Non-spatial means that price and quantity effects resulting from geographic differences in market locations are not included. Therefore, price and quantity effects obtained from the model are assumed to be the average of effects across geographically separated markets. Partial equilibrium means that the model results are based on maintaining a commodity-price equilibrium in a limited portion of the overall economy.

Economic sectors not explicitly included in the model are assumed to have a negligible effect on the model

results. Welfare refers to benefits or losses to society, as measured by changes in consumers' willingness to pay for commodities beyond their actual price (a measure of utility known as consumer surplus) and changes in producers' revenue beyond their variable costs (a measure of returns to fixed investment known as producer surplus).

This quantitative economic modeling approach is appropriate because the rule changes are specific to the U.S. cattle and beef sectors, are focused in extent, and have only limited extensions into non-agricultural sectors of the economy. A disadvantage of the model is the lack of linkages between the cattle production and beef processing sectors. This disadvantage is addressed through the presentation of results from an agricultural multi-sector model that recognizes such linkages.

We estimate effects of additional supplies to the United States of fed cattle and feeder cattle, due to resumption of imports from Canada. The additional quantities of cattle, all things equal, will cause prices to fall. The model indicates the expected price decline and the increase in quantity demanded and decrease in domestic production/supply that will occur in response to the fall in price. Summing welfare gains for consumers/buyers and losses for producers/suppliers (changes in consumer and producer surplus) yields estimated net benefits for the United States. For beef, we expect a small decline in imports from Canada with the rule due to the replacement of beef produced from fed cattle by beef produced from cows, as explained below. Estimated effects for beef are in the opposite direction from those for cattle, with losses for U.S. consumers/buyers outweighing gains for U.S. producers/suppliers. The effects for beef are much smaller than the effects for cattle.

Cattle imports from Canada. There are three components to the number of cattle under 30 months of age that are expected to be imported from Canada: A quantity that would be imported normally, a quantity that would have entered if cattle imports from Canada were not prohibited (termed the backlog); and a quantity of fed cattle that would be expected to be displaced from slaughter in Canada by increased cow slaughter for the export of processing beef to the United States.

For the first component, the quantities of fed and feeder cattle that would enter normally are based on average imports for 2001 and 2002: About 652,400 fed cattle and about 311,400 feeder cattle in 2005, with somewhat lesser quantities

in years 2006–2009 because of assumed expanded slaughter capacity in Canada.

The backlog is the additional Canadian cattle that may have accumulated due to the closing of the border to live ruminant imports in May 2003. Importation of the backlog or some fraction of it would begin as soon as the rule is in effect, with most of these fed and feeder cattle expected to enter in 3 to 6 months.

Calculation of the size of the backlog is based on the change in Canada's cattle inventory from July 2003 to July 2004. The backlog may include about 394,500 fed cattle under 30 months of age and about 204,000 feeder cattle. The backlog of cattle over 30 months of age (not eligible for importation under the rule) numbers about 462,500 head.

The third component of expected cattle imports, an additional supply of fed cattle derives from another change included in the rule—namely, removal of the requirement that beef imported from Canada come from cattle slaughtered at less than 30 months of age. We expect this change to result in a large increase in cow slaughter in Canada for the export of processing beef to the United States. We discuss these expected effects here in greater detail.

Our assumptions regarding (1) the shift in Canada from slaughter of fed cattle under 30 months of age to slaughter of cattle (principally cows) over 30 months of age, for the export of processing beef to the United States, and (2) the shipment to the United States of the fed cattle under 30 months of age not slaughtering in Canada, are based on relative prices and margins in the two countries for fed cattle, cows, fed beef, and processing beef. As of mid-November 2004, a Canadian packer could buy a cow for about US\$17 per cwt and sell the processing-grade beef for about US\$123 per cwt. The packer also could buy a fed steer or heifer at about US\$67 per cwt and sell the beef for about US\$132 per cwt. In the United States, the cow would cost a packer about \$55 per cwt and the beef would sell for about \$125 per cwt; a fed steer or heifer would cost about \$85 per cwt and the beef would sell for about \$135 per cwt.

Although differences in weights and dressing percentages do not permit the direct comparison of live animals to dressed meat, the difference between the relative purchase prices to sales prices indicate that the margin buying cows and selling processing beef is much larger for a Canadian packer than it is for a U.S. packer. Canadian packers are prevented from taking greater advantage of this large margin by Canada's relatively small market for cow

beef. Canadian production of processing beef has already displaced much of Canada's imported product. Without a larger demand, increased production would cause the Canadian price of processing beef to decline sharply.

The United States is already providing Canada with additional demand for beef from fed cattle, through the importation of boneless beef under permit from cattle slaughtered at less than 30 months of age. The United States, in a sense, is currently importing Canada's surplus production of fed beef. Allowing the United States to import Canadian beef from cattle slaughtered at more than 30 months of age would enable Canada to produce and sell much larger quantities of processing beef without fearing the significant price collapse that would likely occur if the entire additional product were only for the Canadian market.

This is not to say that the price of processing beef or cow prices in the United States would not decline from their current levels due to the supply from Canada, but we would not expect a sharp decline. Two facts concerning the U.S. supply of processing beef underlie this reasoning. First, U.S. cow slaughter is forecast to decline in 2005, as producers begin to rebuild herds that have been characterized by diminishing cow inventories for several years. Second, cow retention for herd rebuilding is also expected to take place in Australia and New Zealand, major sources of processing beef for the United States. Their beef exports are forecast to remain largely unchanged in 2005. As long as principal Asian markets continue to prohibit entry of U.S. beef, any increase in imports of beef from Australia and New Zealand by these markets may limit the supply of beef from Australia and New Zealand into the United States.

With the rule, entry of Canadian steers and heifers is expected to result in steer and heifer prices in the two countries becoming more similar. For example, in 2002, fed steer prices in Alberta averaged about US\$63 per cwt, while in the United States, the Nebraska Direct Choice steer price averaged about \$67 per cwt. Given the difference in mid-November 2004 prices for fed cattle, \$67 per cwt in Canada and \$85 per cwt in the United States, shipment of fed cattle to the United States will be an attractive alternative for Canadian producers, at least until Canadian prices rise to the level of U.S. prices (adjusted for grade differentials and minus transportation and transaction costs).

Prices for slaughter cows in the two countries are expected to continue to differ because Canadian cattle more

than 30 months of age will not be allowed entry by the rule, despite a ready market for them at slaughter facilities located in the Northern United States. Thus, in the absence of trade in those cattle, the backlog of cattle over 30 months of age will remain until increased cow slaughter in Canada reduces their inventory. We would expect the price of cows in Canada to increase as slaughter increases in response to opportunities to export beef from cattle more than 30 months of age to the United States. However, the margin earned from slaughtering cows in Canada and exporting the processing beef to the United States is likely to remain favorable (though decreasingly so as Canada's backlog of cattle more than 30 months of age is reduced).

It is assumed that the Canadian slaughter sector is operating at full capacity. Key to assumptions underlying this analysis is the willingness of Canadian slaughter facilities to add cow slaughter shifts or days to their operations at the expense of steer and heifer slaughter. We believe they would want to do so, given the price differentials in Canada and the United States and the opportunity for Canadian beef exports to the United States from cattle slaughtered at more than 30 months of age. With the rule, beef imported from Canada would no longer be required to come from a slaughter facility that either slaughters only cattle less than 30 months of age or complies with an approved segregation process, which may permit increased flexibility in scheduling cow slaughter.

In 2005, APHIS expects this shift by Canada to exports of processing beef and additional fed cattle to the United States to take place throughout the year, not during one or two quarters as assumed for the backlog of steers and heifers under 30 months of age. Beyond 2005, additions to Canadian slaughter capacity are expected to allow increased slaughter of cattle of all ages. Canada has been able to increase its slaughter numbers during the past year, but the opening of new plants and major expansion of current processing facilities to accommodate increased cow slaughter will likely take some years. The lack of excess slaughter capacity in Canada and the described price differentials are the basis for the assumed shift to increased cow slaughter in Canada for the production of processing beef for export to the United States, and the assumed additional imports of Canadian fed cattle.

In 2005, the maximum number of imported fed cattle displaced from

Canadian slaughter may equal the backlog of cattle over 30 months of age (assumed to be slaughtered for the export of processing beef to the United States), about 460,000 head. For years 2006–2009, we assume the number of fed cattle displaced from slaughter in Canada and exported to the United States to decline, as Canada's slaughter capacity increases and Canada's cow prices trend upward. However, all things equal, as long as live cattle imports from Canada are limited to animals less than 30 months of age and the U.S. demand for processing beef is high, beef imports from Canadian cow slaughter may be favored.

Uncertainty surrounds both the assumed backlog quantities and the quantity of fed cattle expected to be displaced by cows slaughtered in Canada and exported to the United States. We acknowledge these uncertainties by also conducting the analysis using one-half of the assumed backlog and one-half of the assumed number of displaced fed cattle.

After the backlog of cattle has been imported, imports of cattle under 30 months of age from Canada are expected to continue at historic levels elevated by the importation of the fed cattle displaced from Canadian slaughter by the slaughter of cows. We therefore expect the largest impact of the rule to occur during the first 3 to 6 months that the rule is in effect. In order to assess these very near-term price impacts, we estimate effects of the rule for the first and second quarters of 2005, in addition to the five-year analysis of welfare effects. As in the analysis of welfare impacts, we acknowledge uncertainty about the quantity of cattle what will enter from Canada by conducting a sensitivity analysis of near-term price effects using one-half of the assumed backlog and one-half of the assumed number of displaced fed cattle.

Beef imports from Canada. Boneless beef entering from Canada under permit represents a large share of historic beef imports from Canada. Before the Alberta BSE discovery, Canada's share of U.S. beef imports was about 41 percent (90 percent of fresh/chilled beef imports and 4 percent of frozen beef imports). Currently, Canada's share of U.S. beef imports is about 32 percent (fresh/chilled beef, 85 percent; frozen, 3 percent). For this reason alone, the effect of the rule for beef imports will be much smaller than the effect for cattle imports. Canadian beef entering the United States by permit is included in the baseline for the analysis.

As described, we expect Canadian cows to be slaughtered in place of fed cattle for the export of processing beef

to the United States, given Canada's limited capability to increase its slaughter capacity in the short term. A cow that is slaughtered produces less meat than a fed steer or heifer due to a lighter weight and lower dressing percentage. Recent statistics from Canada indicate an average difference in beef produced from one steer/heifer and one cow of 150 pounds. In 2005, assuming Canada is fully utilizing all available slaughter capacity, the decrease in beef production would total about 69 million pounds if the backlog of about 460,000 cattle over 30 months of age is slaughtered in place of steers and heifers. To take into consideration possible declines in Canada's domestic consumption of beef as beef prices rise slightly relative to other meats, and therefore movement of beef from the domestic to export markets, we reduce the decline of 69 million pounds by one-third, to 46 million pounds.

The forecast for Canada's beef exports worldwide in 2005 is 570,000 metric tons. U.S. imports of beef from Canada are forecast to equal about 86 percent of Canada's total beef exports, or about 490,200 metric tons. The 490,200 metric tons is equivalent to 1,081 million pounds. In other words, Canada's beef exports to the United States, compared to what would have been exported without this rule, can be expected to decline in 2005 by 4.3 percent (46 million pounds divided by 1,080 million pounds) because of the displacement of steer/heifer slaughter by cow slaughter in Canada. The decrease in Canadian beef exports to the United States because of this displacement is assumed to diminish in years 2006–2009, as Canada's slaughter capacity expands.

Processing-grade beef is not perfectly substitutable for fed beef. The two commodities compete in different but closely related markets. This distinction is not included in the analysis because the model is based on aggregate beef price ranges and elasticities. Increased supplies of processing beef are expected to compete with fed beef in the same fashion as other close substitutes. Thus, allowing imports of beef from cattle slaughtered at over 30 months of age, together with fed cattle imports augmented by the cattle displaced from Canadian slaughter, is expected to result in lower prices for U.S. steers and heifers.

As with the assumed backlog and displaced fed cattle imports, there is uncertainty as to the amount of beef from Canadian cow slaughter that will be imported by the United States. Accordingly, we include in the sensitivity analysis a reduction by one-

half of the assumed change in beef imports from Canada. In 2005, for example, this reduced amount would represent a decrease in beef imports from Canada of 2.1 percent from what

would have been imported without the rule.

Welfare and Near-term Price Effects of the Rule for Cattle and Beef

Welfare effects. Welfare effects of the rule for cattle and beef are summarized

in Table 1. Present values and annualized values of welfare gains and losses over the five-year period 2005–2009, are determined using 3 percent and 7 percent discount rates, in both 2005 and 2001 dollars.

TABLE 1.—PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	\$2,982,088	–\$2,907,462	\$74,626
	7	2,592,201	–2,525,852	66,349
Present, 2001 dollars	3	2,810,618	–2,740,283	70,335
	7	2,443,150	–2,380,616	62,534
Annualized, 2005 dollars	3	651,153	–634,858	16,295
	7	632,214	–616,032	16,182
Annualized, 2001 dollars	3	613,711	–598,353	15,358
	7	595,861	–580,610	15,251

Note: The present and annualized values are taken from Appendix H, based on assumed import of the backlog, import of fed cattle displaced from slaughter in Canada by increased cow slaughter for the export of processing beef to the United States, and beef imports from cows slaughtered in place of fed cattle.

The present value of the net benefit of the rule for cattle and beef is estimated to range in 2005 dollars between \$66.3 million and \$74.6 million, depending on the discount rate used. Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, ranges between \$16.2 million and \$16.3 million.

The largest effects for cattle are expected to occur in 2005, when the backlog would be imported and the displacement of fed cattle slaughter by cow slaughter would be largest. The impact for fed cattle would be greater than for feeder cattle because of the larger number of fed cattle expected to be imported. For fed cattle, the annual price declines may range from an average of 3.2 percent in 2005 to 1.3 percent in 2009. For feeder cattle, the price declines range from an average of 1.3 percent in 2005 to 0.6 percent in 2009.

Estimated net benefits in 2005 for fed cattle are estimated to range from \$25.0 million to \$26.9 million, and for feeder cattle, from \$10.4 million to \$11.0 million. In each successive year, the net benefits are expected to become smaller,

such that by 2009 they may range for fed cattle from \$3.8 million to \$4.3 million, and for feeder cattle, from \$4.3 million to \$4.8 million.

Effects of the rule for beef attributable to the change in beef imports from Canada are expected to be much smaller than those for cattle. For example, the expected 2005 net welfare loss (because of the decline in imports due to cow slaughter replacing fed cattle slaughter) in 2005 dollars is estimated to range between \$94,000 and \$98,000. Average percentage increases in price may range from 0.09 percent in 2005 to 0.01 percent in 2009, suggesting nearly negligible impacts. If the beef-equivalent of the fed and feeder cattle imported from Canada is considered, the supply of beef in the United States increases and the price of beef decreases by 1 to 2 percent from 2005 baseline levels. Smaller decreases from baseline projections would occur after 2005 because the volume of imported animals declines.

Effects may be even smaller for U.S. producers than these percentages indicate, given that nearly all U.S. beef imports from countries other than

Canada consist of processing beef. Demand for imported processing beef has increased drastically as ground beef sales continue at a robust pace. At the same time, U.S. production of processing beef has fallen to record lows because of the cyclical decline in cow slaughter.

Table 2 shows the results of the sensitivity analysis, assuming importation of one-half of the backlog, one-half of the fed cattle expected to be displaced from slaughter in Canada, and one-half of the expected replacement of fed cattle beef imports derived from fed cattle by beef imports derived from cows. The present value of the net benefit for cattle and beef in this case is estimated to range in 2005 dollars between \$48.9 million and \$56.1 million, depending on the discount rate used. Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, may range between \$11.9 million and \$12.3 million—that is, about three-fourths of the expected annualized net benefit with the rule.

TABLE 2.—SENSITIVITY ANALYSIS BASED ON REDUCED IMPORT QUANTITIES: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	\$2,571,323	–\$2,515,180	\$56,144
	7	2,211,115	–2,162,168	48,947
Present, 2001 dollars	3	2,423,472	–2,370,557	52,915
	7	2,083,976	–2,037,844	46,132

TABLE 2.—SENSITIVITY ANALYSIS BASED ON REDUCED IMPORT QUANTITIES: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS, 2005–2009—Continued

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Annualized, 2005 dollars	3	561,460	–549,201	12,259
	7	539,270	–527,333	11,938
Annualized, 2001 dollars	3	529,176	–517,622	11,554
	7	508,262	–497,011	11,251

Note: The present and annualized values are midpoints taken from Appendix I, based on assumed imports of one-half of the backlog, one-half of the fed cattle numbers, and one half of the replacement of fed cattle beef imports by cow beef imports.

In this scenario, the impact in 2005, in particular, would be smaller because of the fewer cattle imported. For fed cattle, the annual price declines may range from 2.3 percent in 2005 to 1.2 percent in 2009. For feeder cattle, the price declines over the five-year period may average 0.7 percent. Estimated net benefits in 2005 for fed cattle may range from \$12.9 million to \$13.9 million, and for feeder cattle, from \$8.0 million to \$8.5 million. In each successive year, the net benefits are expected to become smaller, such that by 2009 they may range for fed cattle from \$3.5 million to \$3.9 million, and for feeder cattle from \$4.3 million to \$4.8 million.

The estimated percentage decrease in the price of fed cattle, if one-half of the backlog and one-half of the fed cattle expected to be displaced from slaughter in Canada were imported, would be about 1 percent less than when we assume importation of the full backlog and full quantity of displaced fed cattle (2.3 percent decrease compared to a 3.2 percent decrease). For feeder cattle, the difference in the effect is smaller in absolute terms, but larger in relative terms (0.6 percent decrease compared to a 1.3 percent decrease). In both cases the effects are expected to diminish over the five-year period.

Near-term price effects. As expected, price effects are larger when the backlog is assumed to enter in one quarter rather than two quarters, and are larger for fed cattle than for feeder cattle, given the larger number of fed cattle expected to be imported. For example, for fed cattle, the decrease in price when the backlog is assumed to enter entirely within one quarter is estimated to be 5.4 percent, assuming a price elasticity of supply of 0.61 and a price elasticity of demand of –0.76. When the backlog of fed cattle is assumed to enter over two quarters using the same price elasticities, the decline in price is estimated to be 3.8 percent. Entry of the backlog of feeder cattle over the two quarters could result in price declines of 1.9 percent, for the same elasticities, compared to a possible

price drop of 3.3 percent when the enter entirely within one quarter.

The less elastic the price elasticities (the less responsive sellers and buyers are to price changes), the larger the expected percentage changes in price. When the supply and demand elasticities are halved (supply elasticity of 0.30 and demand elasticity of –0.38), for example, and fed cattle are assumed to enter within two quarters, the decrease in price could be 4.8 percent, compared to a price decrease of 3.8 percent when a supply elasticity of 0.61 and demand elasticity of –0.76 are used.

When the assumed backlog and assumed number of imported fed cattle displaced from Canadian slaughter are halved as a sensitivity analysis, the near-term price effects are found to be smaller overall, with the smaller elasticities again yielding larger price decreases. For example, the percentage decrease in price for fed cattle entering over two quarters is estimated to be 2.5 percent for a supply elasticity of 0.61 and a demand elasticity of –0.76 (compared to a 3.8 percent price decline when the full backlog and number of displaced fed cattle are imported). If the supply elasticity were 0.30 and the demand elasticity were –0.38, the price decline is estimated to be 3.2 percent (compared to 4.8 percent for the full cattle import numbers). Similarly, smaller percentage price declines are observed for feeder cattle when in the sensitivity analysis the backlog and the number of imported fed cattle displaced from Canadian slaughter are halved.

Other Impacts of the Rule

We consider other effects of the rule besides those estimated for cattle and beef, including: The results of an agricultural multi-sector analysis; costs that may be incurred in monitoring the movement of imported Canadian feeder ruminants; effects for ruminant products other than cattle and beef; and possible effects of the rule on U.S. exports.

Multi-sector analysis. Some commenters on the analysis for the proposed rule emphasized the integrated structure of the cattle and beef processing industries, and noted potential effects of the rule on other sectors of the economy. APHIS agrees that a multi-sector analysis can capture industry interactions that are missing from single-sector analyses. We therefore report the results of an analysis based on a model that includes the animal feed, animal production, and animal product processing sectors.

While the major vertically linked marketing channels are included in this model, effects of the rule farther downstream in the economy are not modeled. For example, economic benefits to surrounding communities of increased employment in slaughter plants receiving greater supplies of cattle due to reopening of the Canadian border are not captured by the model, nor are similar economic losses resulting from reduced spending in communities by cattle producers due to reductions in their returns. These effects are believed to be very small on a national basis, but may show some geographic concentration.

The multi-sector analysis simulates percentage changes in prices and gross revenues (price multiplied by the quantity sold) using the assumed 2005 range of imported Canadian cattle (roughly 1.5 million to 2 million head, fed and feeder cattle combined). The results of the analysis show for the combined livestock, feed, and grain sectors, a possible decline in gross revenues of 1.4 percent to 1.7 percent. For the beef and cattle sectors, the gross revenue declines may range from 1.3 percent to 1.6 percent, and from 3.9 percent to 4.8 percent, respectively.

With respect to the change in the price of cattle in 2005, the multi-sector analysis indicates a possible decline of between 3.3 percent and 4.1 percent, compared to 2005 price declines estimated in the single-sector analyses of between 0.6 percent and 1.3 percent

for feeder cattle, and between 2.3 percent and 3.2 percent for fed cattle. To the extent that sector interactions result in expanded effects as indicated by these relative price declines, welfare gains and losses will be larger than are indicated in Table 1. The multi-sector model simulates price and revenue changes, but does not yield measures of welfare change. However, this model does indicate a decline in consumer expenditures by about 1 percent, a finding that supports the estimated consumer welfare gains attributable to the rule.

The multi-sector analysis also examines possible effects if beef consumption in the United States were to decline by 2 percent because of consumers' perception of increased risk of BSE with the rule. Compared to the assumption of no consumer response, this scenario shows that there would be a decline in beef and cattle prices by an additional 0.2 percent to 0.4 percent, causing gross revenues for the beef and cattle sectors to fall by an additional 0.2 percent to 0.5 percent.

A third scenario considered in the multi-sector analysis is partial restoration of beef exports to Japan, such that U.S. beef exports in 2005 would double, from an expected 0.3 million metric tons to 0.6 million metric tons. In this instance, gross revenue for the cattle sector (assuming 1.5 million head of Canadian cattle are imported) could decline by 1.7 percent, compared to a possible decrease of 3.9 percent assuming no change in U.S. beef exports. For the beef sector, gross revenue losses of 1.3 percent may become gains of 2.2 percent because of the exports to Japan. For both sectors, increased U.S. exports could moderate by at least one-half the price declines due to resumption of cattle imports from Canada.

Monitoring the movement of feeder cattle. Movement within the United States of feeder cattle (and feeder lambs and goats) imported from a BSE minimal-risk region such as Canada—from the U.S. port of entry to a feedlot and from the feedlot to slaughter—will require that certain inspection and record keeping safeguards be satisfied. The increased cost of these requirements is considered a cost to this rulemaking. These include certification of each animal's identification (by eartag and branding), age, and feeding history. Feeder cattle will be listed on the APHIS Form VS 17-130 that accompanies the animals from the port of entry and on the APHIS Form VS 1-27 that accompanies the animals to slaughter.

Costs of the process can be approximated by considering the time Federal or State officials or their designees would spend monitoring the movement of these cattle. We approximate the cost of performing the inspections and related tasks to be \$10 per animal, based on direct salary, personnel benefits, administrative support costs, agency overhead, and departmental charges, and using a simplified example developed by APHIS Veterinary Services. Given the number of feeder cattle that may enter because of the rule, the overall cost in 2005 would be between \$4.1 million and \$5.2 million.

Commodities other than cattle and beef. Other, less major commodities that will be allowed entry under the rule and for which we have data are sheep, goats, and farmed cervids; meat from these ruminants; and bovine tongues and livers. In all cases, reestablished imports from Canada will have small effects on the U.S. supply of these commodities and the welfare of U.S. entities. Feeder lambs and goats will be required to be moved to designated feedlots. As with feeder cattle from Canada, movement of feeder lambs and goats from the port of entry to feedlot and from feedlot to slaughter will be monitored, which will lead to a small cost.

U.S. exports. The rule, of course, will have no immediate effect for U.S. exports to countries that currently prohibit beef imports from the United States. It could influence these countries' future decisions regarding resumption of beef imports from the United States. A country may consider the rule to lend justification to a decision to continue to prohibit entry of U.S. beef because of concern about BSE risks posed by Canadian cattle, even though there would be no scientific basis. In such a case, there would be continued premium losses over and above the domestic value of the products, especially for beef variety meats. On the other hand, resumption of U.S. imports from Canada may help convince other countries of the sanitary safety of both U.S. and Canadian beef. Any effects the rule may have for future U.S. beef exports may vary from one trading partner to another.

Alternatives to the Rule

Alternatives to the rule would be to leave the regulations unchanged—that is, continue to prohibit entry of ruminants and most ruminant products from regions of minimal BSE risk (other than products allowed entry under permit), or modify the commodities and/or import requirements specified in the rule. By maintaining current import

restrictions, the net benefits of reestablishing imports from Canada of fed and feeder cattle, and beef not by permit, and other affected commodities would not be realized. Two possible modifications would be to (i) require that imported beef come from cattle slaughtered at less than 30 months of age, or (ii) continue to prohibit the entry of live ruminants.

Beef only from cattle less than 30 months of age. The proposed rule would have required beef imports from Canada to come from cattle slaughtered at less than 30 months of age. In a notice that reopened the comment period for the proposed rule, APHIS stated that it no longer believed that it would be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided measures are in place to ensure that SRMs are removed when the animals are slaughtered, and that such other measures as are necessary are in place. Canada is removing SRMs at slaughter and fulfilling other required measures.

Requiring that beef come only from cattle slaughtered at less than 30 months of age would continue the prohibition on Canadian cows and bulls as source animals, and eliminate effects of the rule for beef. Continuing to limit imports from Canada to veal from calves and beef from steers and heifers would cause Canada's cow and bull inventories to continue to grow and exert downward pressure on Canada's cow prices, which are already well below U.S. price levels. Canadian suppliers would be prevented from participating in the current high-demand market in the United States for processing beef, and U.S. processors would not benefit from the additional source of supply during a time when U.S. cow slaughter is cyclically low.

This alternative would maintain the status quo in terms of beef imports, other than removing permit requirements and broadening the commodities allowed to be imported beyond boneless beef. In terms of the quantity of beef imported, we expect that these changes would have a very small effect, given the large share of Canada's historic exports that enter currently.

This alternative would affect cattle imports from Canada by removing the incentive for Canadian cows to be slaughtered in place of fed cattle, since the processing beef would not be allowed to be imported by the United States; there would not be the displaced fed cattle assumed to be available for import under the rule. The number of fed cattle imports would be fewer than

with the rule, especially in 2005, and price and welfare impacts, including net benefits, would be smaller.

Welfare effects of this alternative for cattle and beef are summarized in Table 3. Present values and annualized values of welfare gains and losses over the five-

year period 2005–2009 are determined using 3 percent and 7 percent discount rates in both 2005 and 2001 dollars.

TABLE 3.—ALTERNATIVE OF CANADIAN BEEF IMPORTS ONLY FROM CATTLE LESS THAN 30 MONTHS OF AGE: PRESENT AND ANNUALIZED VALUE ESTIMATIONS OF THE EFFECTS OF THE RULE FOR FED CATTLE, FEEDER CATTLE, AND BEEF, DISCOUNTED AT 3 PERCENT AND 7 PERCENT, IN 2005 AND 2001 DOLLARS 2005–2009

Value	Discount rate (percent)	Changes in welfare (per thousand dollars)		
		Consumer	Producer	Net
Present, 2005 dollars	3	\$2,399,299	– \$2,345,160	\$54,139
	7	2,064,181	– 2,016,794	47,387
Present, 2001 dollars	3	2,261,339	– 2,210,314	51,026
	7	1,945,490	– 1,900,828	44,662
Annualized, 2005 dollars	3	523,898	– 512,076	11,821
	7	503,434	– 491,877	11,557
Annualized, 2001 dollars	3	493,774	– 482,632	11,142
	7	474,487	– 463,594	10,893

Note: The present and annualized values are midpoints taken from Appendix U, based on the assumed backlog imports.

The present value of the net benefit of the alternative for cattle and beef is estimated to range in 2005 dollars between \$47.4 million and \$54.1 million, depending on the discount rate used (with the rule: Between \$66.3 million and \$74.6 million). Over the five-year period, the annualized value of the net benefit in 2005 dollars, depending on the discount rate, may range between \$11.6 million and \$11.8 million (with the rule: Between \$16.2 million and \$16.3 million).

The largest effects for cattle are expected to occur in 2005, when the backlog is imported. Since allowing Canadian beef imports only from cattle slaughtered at less than 30 months of age would not affect the number of feeder cattle expected to be imported, effects for feeder cattle would be the same as with the rule.

Possible effects of this alternative for future U.S. exports would differ from possible effects with the rule only if other countries perceived BSE-risks associated with Canadian beef produced from cattle slaughtered at less than 30 months of age as different from those associated with Canadian beef produced from cattle slaughtered at more than 30 months of age.

There would be no known reduction in risk of BSE introduction under this alternative. Removal of SRMs at slaughter and other required risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.

Near-term price effects of this alternative would be similar to those of this rule. For example, for fed cattle the decrease in price when the backlog is assumed to enter entirely within one

quarter is estimated to be 4.4 percent (with the rule: 5.4 percent), assuming a price elasticity of supply of 0.61 and a price elasticity of demand of –0.76. When the backlog of fed cattle is assumed to enter over two quarters using the same price elasticities, the decline in price is estimated to be 2.8 percent (with the rule: 3.8 percent). Entry of the backlog of feeder cattle over the two quarters could result in a price decline of 1.9 percent under this alternative and using the same elasticities, compared to a possible price drop of 3.3 percent when the backlog is assumed to enter entirely within one quarter. The expected effects are the same for feeder cattle under this alternative and with the rule because their number is assumed to be unaffected by whether Canadian beef imports are restricted to being derived from cattle less than 30 months of age. When the supply and demand elasticities are halved (supply elasticity of 0.30, and demand elasticity of –0.38, for example, and fed cattle are assumed to enter within two quarters, the decrease in price is estimated to be 3.6 percent (with the rule, 4.8 percent), compared to a decrease of 2.8 percent (with the rule, 3.8 percent) when a supply elasticity of 0.61 and demand elasticity of –0.76 are used.

No live ruminants. Direct effects of this alternative would be equivalent to expected effects of the rule only for ruminant products. We would expect the same effect for beef as with the rule; imports of beef from cows would replace imports of beef from fed cattle, yielding, for the five-year period 2005–2009, present value losses for consumers of between \$73.9 million and \$78.8 million, gains for producers of

between \$73.7 million and \$78.5 million, and net welfare losses of between \$264,000 and \$283,000, compared to the baseline (3 percent discount rate, 2005 dollars). There would also be net benefits forgone by the continued prohibition on the importation of sheep and goats. Possible effects of this alternative on future U.S. exports would likely be small, since it would maintain the current prohibition on imports of live ruminants from Canada.

In sum, the rule is preferable in terms of expected net benefits to the status quo (continuing to prohibit the entry of Canadian ruminants, and the entry of Canadian ruminant products other than those allowed by permit), and to the two alternatives discussed: Limiting beef imports to cattle slaughtered at less than 30 months of age or allowing entry of ruminant products but not live ruminants. Risks of BSE introduction would not be reduced to any known degree by selecting one of the alternatives in place of the rule. We believe that listing Canada as a minimal-risk region subject to the required risk-mitigating measures is a balanced response, based on scientific evidence, to Canada's request that certain ruminant and ruminant product imports by the United States be allowed to resume.

Final Regulatory Flexibility Analysis

As a part of the rulemaking process, APHIS evaluates whether regulations are likely to have a significant economic impact on a substantial number of small entities. The resumption of ruminant and ruminant product imports from Canada will most importantly affect the cattle industry, reducing prices and increasing supplies. Entry of fed cattle

(and fed sheep and goats) will benefit U.S. slaughtering establishments, and entry of feeder cattle (and feeder sheep and goats) will benefit feedlots. Also, entry of beef from cattle slaughtered at over 30 months of age will benefit some U.S. meat and meat product wholesalers and packers by providing an additional source of processing beef. At the same time, these imports will increase the competition for U.S. and foreign suppliers of these commodities.

The main industries expected to be affected by the rule are composed predominantly of small entities, as indicated by the 1997 Economic Census, the 2002 Census of Agriculture, and USDA's "Cattle on Feed" (February 20, 2004). The small entities number in the hundreds of thousands, with cattle producers comprising the largest number. For beef cattle ranching and farming, the 2002 Census of Agriculture indicates a total of about 657,000 operations, of which nearly 656,000 are considered small entities. For cattle feedlots, more than 91,000 of the approximately 93,200 total operations are small entities. For sheep and goat farming, 44,000 out of about 44,200 operations are considered small entities. Small entities similarly dominate, in terms of percentage operations, other affected industries, including animal slaughtering, meat and meat byproduct processing, and meat and meat product wholesaling.

Notwithstanding the prevalence of small entities, the concentrated structure of affected industries is well-documented. In the U.S. meatpacking industry, for example, four firms handle nearly 80 percent of all steer and heifer slaughter. The cattle feedlot industry is also highly concentrated. Data from 2003 show that only 2 percent of feedlots have capacities greater than 1,000 head, and yet these larger feedlots market 85 percent of fed cattle.

Imports from Canada that will be allowed to resume are expected to have a larger effect on the fed cattle market than on the feeder cattle market. Prices and welfare of producers and suppliers will decline because of the additional supply and the welfare of consumers and buyers will increase. Net benefits of the rule will be positive.

The analysis provides an estimation of possible price effects for small-entity and other producers and processors during the first 3 to 6 months that the rule is in effect, when impacts may be greatest due to the expected importation of the backlog. Depending on the assumed elasticities of supply and demand and the period over which the backlog enters, the estimated price declines could range from 1.9 percent to

4.4 percent for feeder cattle and from 3.8 percent to 6.9 percent for fed cattle. For the year 2005, the model indicates a possible decline in feeder cattle prices of 1.3 percent and a possible decline in fed cattle prices of 3.2 percent.

To give these average percentage price decline some perspective, we consider as an example their effect on earnings by small U.S. beef cow herds. Based on data from the 2002 Census of Agriculture, the average value of sales of cattle and calves by small-entity beef cow operations was about \$26,700. Given the forecast feeder cattle baseline price for 2005 of between \$94 and \$100 per cwt, the 2005 estimated price decline of 1.3 percent would be equivalent to a decrease of between \$1.22 to \$1.30 per cwt, or a decrease in annual revenue of between \$326 and \$347, assuming no reduction in the number of cattle marketed. This example abstracts from the wide range in size for small beef cow herds, but gives an indication of a possible average price effect of the rule for these operators in 2005. It should be recognized that while the decline in price would be a loss for producers, it would represent a gain for small-entity feedlot operators.

Beyond the net welfare gains as summarized in Table 1, there will likely be regional impacts not captured in the analysis. Among comments received on the proposed rule were ones that pointed out the historical reliance of some northern U.S. meat processing plants (and the communities they support) on cattle imports from Canada to maintain necessary throughput volumes. Historical dependence of these processing facilities on cattle imports from Canada exemplifies economic ties with Canadian entities that existed prior to the prohibition on ruminant imports. Resumption of imports will enable trade relationships involving small-entity operations to be reestablished.

Alternatives to the rule, whether leaving the regulations unchanged or modifying the commodities and/or import requirements specified in the rule, would benefit certain categories of small entities while harming others. For example, a continued prohibition on the importation of Canadian feeder cattle would benefit small-entity suppliers of feeder cattle, but at the expense of small-entity feedlot operators. Estimated price declines, particularly in the near term, will cause economic losses for some entities and at the same time benefit other entities. Overall, the analysis indicates the rule will have a net positive effect for the United States.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801–808). Accordingly, the effective date of this rule has been delayed the required 60 days pending congressional review.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

In October 2003, APHIS prepared an environmental assessment to consider potential impacts to the human environment from implementation of the proposed rulemaking. During the comment period for the proposed rulemaking, comments were received from the public regarding the environmental assessment. As a result of those comments, APHIS revised the environmental assessment to discuss in more detail the potential impacts of concern for the human environment.

The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

APHIS sent copies of the revised environmental assessment to those who commented on the October 2003 environmental assessment, in accordance with 7 CFR 372.9(a)(3). In a separate notice in today's issue of the **Federal Register**, APHIS is announcing the availability of the revised assessment and is requesting comments on the revised assessment for 30 days.

Paperwork Reduction Act

This final rule includes certain regulatory provisions that differ from those included in the November 2003 proposed rule. Some of those provisions involve changes from the information collection requirements set out in the proposed rule. These changes include

Rules and Regulations

Federal Register

Vol. 68, No. 103

Thursday, May 29, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93 and 94

[Docket No. 03-058-1]

Change in Disease Status of Canada Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations by adding Canada to the list of regions where bovine spongiform encephalopathy exists because the disease has been detected in an animal in that region. This action prohibits or restricts the importation of ruminants that have been in Canada and meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. This action is necessary to help prevent the introduction of bovine spongiform encephalopathy into the United States.

DATES: This rule is effective retroactively to May 20, 2003. We will consider all comments that we receive on or before July 28, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03-058-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 03-058-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and

address in your message and "Docket No. 03-058-1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of cattle and is not known to exist in the United States. It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants with BSE are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists or in which there is

an undue risk of introducing BSE into the United States. Paragraph (a)(1) of § 94.18 lists the regions in which BSE exists. Paragraph (a)(2) lists the regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. Paragraph (b) of § 94.18 prohibits the importation of fresh, frozen, and chilled meat, meat products, and most other edible products of ruminants that have been in any region listed in paragraphs (a)(1) or (a)(2). Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of these regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of those regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of these regions. Additionally, the regulations in part 93 pertaining to the importation of live animals provide that the Animal and Plant Health Inspection Service (APHIS) may deny an application for a permit for the importation of ruminants from regions where a communicable disease such as BSE exists and from regions that present risks of introducing communicable diseases into the United States (see § 93.404(a)(3)).

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. Therefore, in order to prevent the introduction of BSE into the United States, we are amending § 94.18(a)(1) by adding Canada to the list of regions where BSE is known to exist. This action prohibits or restricts the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. We are making this amendment effective retroactively to May 20, 2003, which is the date that Canada reported the BSE case.

As noted previously, the regulations in § 93.404(a)(3) provide the basis for APHIS to deny an application for a permit for the importation of ruminants from regions listed in § 94.18(a)(1) or (a)(2). Because, with certain exceptions, ruminants may not be imported into the

United States unless their importation is authorized by a permit, the provisions of § 93.404(a)(3) have been sufficient to prevent the entry of live ruminants from regions affected with BSE. However, the regulations in part 93 provide exemptions from the permit requirement for ruminants from several regions, including Canada, under certain circumstances. Given that the denial of a permit application may not serve in all cases to provide a regulatory basis for preventing the importation of ruminants from regions affected with BSE, we have amended the regulations in § 93.401, "General prohibitions; exceptions," to include an explicit prohibition on the importation of ruminants that have been in any region listed in § 94.18(a)(1) or (a)(2).

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction of BSE into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the *Federal Register*.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the *Federal Register*. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effective to May 20, 2003; and (3) does not require administrative

proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93 and 94 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 93.401, paragraph (a) is revised to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter;³ nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that has been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter is prohibited. *Provided, however,* the Administrator may upon request in specific cases permit ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will

³ Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

not endanger the livestock or poultry of the United States.

* * * * *

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 3. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.18 [Amended]

■ 4. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word "Canada,".

Done in Washington, DC, this 23rd day of May, 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13440 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–109–3]

Importation of Beef From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence presented in a recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action will provide for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit

CERTIFICATE OF SERVICE

I hereby certify that, on the 1st day of July, 2005, I have caused two copies of the Answering Brief of Ranchers Cattlemen Action Legal Fund United Stockgrowers of America and one copy of its Supplemental Excerpts of Record to be served by Federal Express upon:

Joshua Waldman, Esq.
Appellate Litigation Counsel
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Room 7232
Washington, D.C. 20530
(202) 514-0236
Attorney for Government
Defendants/Appellees

Mark Steger Smith
Assistant United States Attorney
Office of the United States Attorney
P.O. Box 1478
2829 3rd Avenue North, Suite 400
Billings, Montana 59101
(406) 247-4667
Attorney for Government
Defendants/Appellees

Simeon M. Kriesberg
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
Attorney for Appellant Alberta Beef
Producers

Edward J. Farrell
Blank Rome LLP
600 New Hampshire Ave., N.W.
Washington, DC 20037
Attorneys for Appellant Canadian
Cattlemen's Association



Russell S. Frye